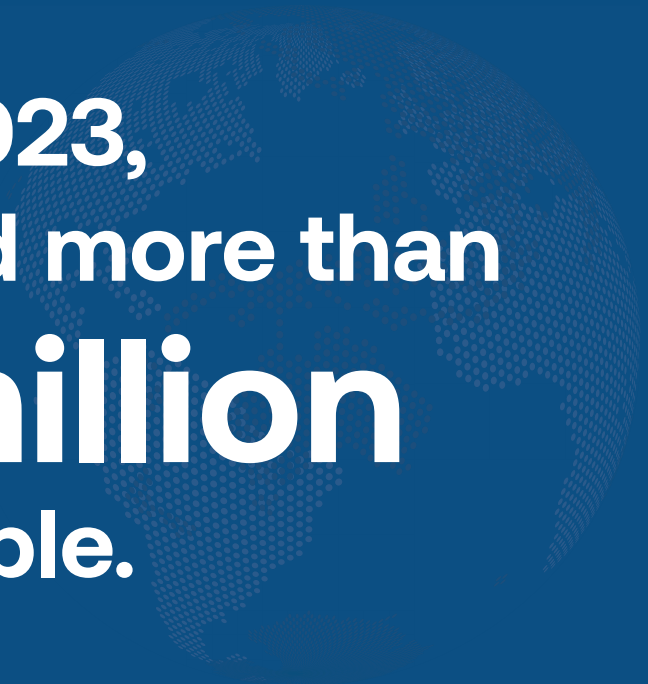
moderna

annual report

2023

moderna® by the numbers



In 2023,
we impacted more than
100 million
people.

Delivering commercial impact



$6.7B
in net **product sales** in 2023

48%
U.S. COVID retail **market share** in fall 2023

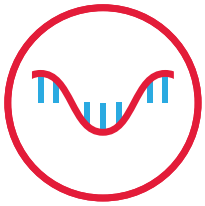
$13.3B
in **cash, cash equivalents and investments** as of December 31, 2023

Advancing our pipeline

4
therapeutic areas

45
development programs

9
late-stage programs





Creating a unique and diverse organization

5,600
employees in 19 markets

49%
women in our workforce

39%
of **executives** are women

Celebrating our culture

2nd
consecutive year of **equal pay** for equal work study showing **no significant differences in pay**

9
years in a row as a *Science* top employer

No. 1
ranked large company in *BioSpace* **Best Places to Work**



Table of contents

05 A letter from our CEO

16 Advancing mRNA respiratory vaccines

18 A new frontier in cancer care

20 Pipeline

26 Building our team

28 Digitizing everywhere

29 Responsibility

32 Leadership

33 Awards and recognition

34 Financials

A letter from our CEO

January 2, 2024
Cambridge, Mass., U.S.A.



> **"As we reflect on the past year, our commitment to leveraging mRNA to deliver transformative medicines for patients has never been stronger."**

Stéphane Bancel,
Chief Executive Officer

Dear fellow shareholders,

Our mRNA platform is working.

Today, we are seeing the high-case scenario from our 2018 five-year, long-range plan unfold. We have demonstrated the potential for clinical benefit in multiple infectious disease vaccines, in skin cancer and in three different rare genetic diseases. Based on these clinical successes, we have advanced a broad and diverse pipeline.

We advanced nine programs into late-stage development, including one approved, one filed for approval, and three more that have completed Phase 3 enrollment. We are many steps closer to reaching millions more people with unmet medical needs.

Through more than a decade of progress and investment in science, Moderna has led in establishing the field of mRNA medicine. The team has built a remarkable platform to scale Moderna at a pace not seen before in our industry. Now, it is up to us to bring these mRNA medicines to market for patients, and consequently to drive value for our shareholders.

As we reflect on the past year, our commitment to leveraging mRNA to deliver transformative medicines for patients has never been stronger. We have the platform, technology, resources and the team to establish a new era of medicine.

A Year of Transition

In 2023, SARS-CoV-2 continued to evolve. The virus that causes COVID-19 is clearly here to stay—just like influenza. Our business has also adapted to a more predictable, seasonal endemic market.

Managing the transition took significant effort in 2023. As you know, we rapidly scaled our manufacturing capabilities during the pandemic to play a critical role in combatting COVID-19 with our vaccine. We knew that this surge capacity may not be required in the endemic market, but we felt obligated to ensure we protected as many lives as we could during the pandemic.

During 2023, it became clear that demand for vaccines had entered a new stage of the endemic setting and we pivoted to significantly resize our manufacturing infrastructure to help ensure our COVID-19 franchise would be profitable in 2024 and beyond. Although undervaccination has been observed in the first endemic season, we believe this will settle out over the coming years as the impact of the virus and vaccine during endemic periods becomes evident and may affect future levels of vaccination.

At the same time, we invested in our people, processes, and digital systems to help us build Moderna for the long term. We opened a technology hub in Seattle and welcomed Brad Miller as Chief Information Officer, emphasizing our continued focus on building digital-first and investing in AI because of the profound impact it will have on our Mission. To further advance our mRNA science, we also entered into a partnership with IBM to explore quantum computing and generative AI. We believe that AI will be as transformational to any business as the desktop computer was when it entered the corporate world.

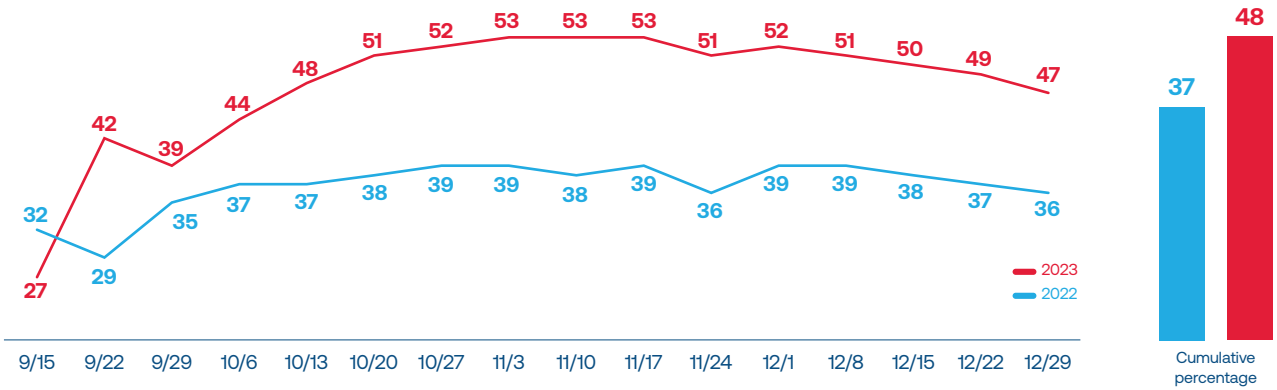
Additionally, we announced a strategic partnership with the Coalition for Epidemic Preparedness Innovations (CEPI), harnessing the power and speed of Moderna's mRNA platform to accelerate the development of mRNA vaccines against viral disease outbreaks that pose global public health threats. The expansion of our mRNA Access program reinforces our dedication to public health by providing researchers with our mRNA technology in the development of vaccines for emerging and neglected infectious diseases. We believe this program can play a key role in helping the next generation of researchers and engineers to advance mRNA science.

We also announced the acquisition of Japan-based OriCiro Genomics, which we now have integrated into Moderna as Moderna Enzymatics. That technology will enable us to reduce manufacturing cycle times and improve quality. We also established strategic collaborations with CytomX, Generation Bio, Immatics and Life Edit, to enhance our internal research and development.

Delivering the Greatest Possible Impact

Last year, we provided external guidance for Spikevax sales of at least $6 billion. We continued to focus on public health efforts to increase vaccination rates globally, and in the U.S. we achieved 48 percent market share for the 2023 fall season, compared to 37 percent in fall 2022—demonstrating our ability to compete in the commercial market. Recognizing that COVID is not going away, we are making it an important piece of our business with our vaccines against COVID-19 and our investigational combination vaccine against flu and COVID.

Spikevax U.S. Retail Administrations Market Share (%)



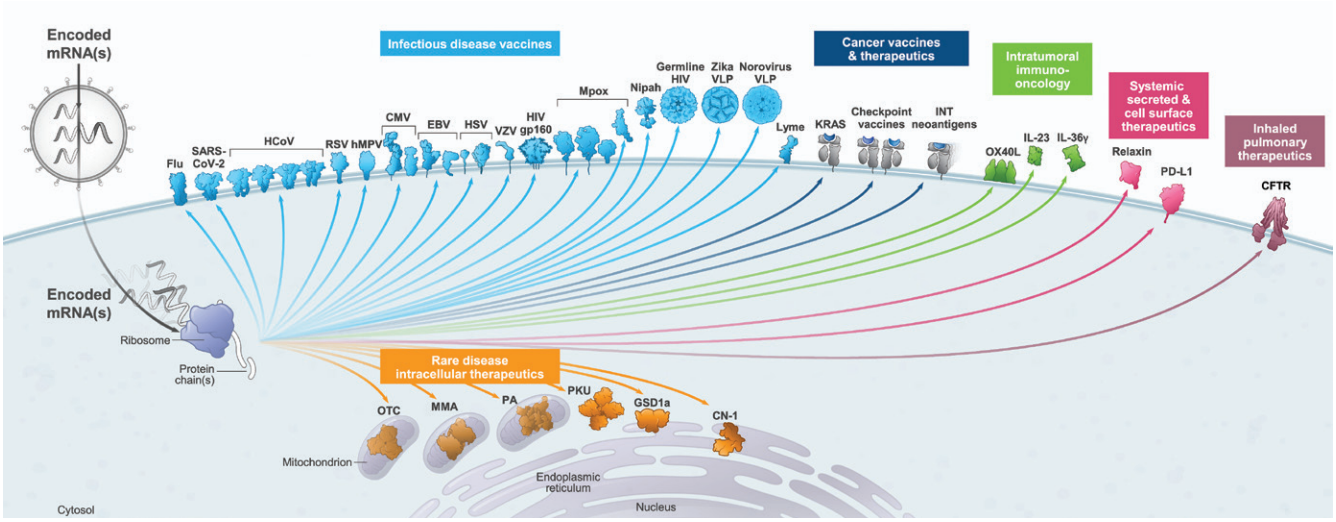
Source : Based on information licenced from IQVIA: IQVIA RAPID Weekly Audit for September-December 2022 and September-December 2023, reflecting estimates of real-word activity. 2022 figures have been aligned to closest corresponding 2023 figures, based on weeks following approval/launch. All rights reserved.

In parallel, we prepared for the potential 2024 launch of our investigational RSV vaccine for adults, which is expected to further strengthen our financial position and further demonstrate the commercial potential of our mRNA platform. We believe our RSV vaccine candidate has a potentially best-in-class profile based on clinical trial data and ready-to-use pre-filled syringes when compared to two recently launched products. In addition, the mRNA vaccine technology that our RSV vaccine uses has a well-established safety and tolerability profile, having been used in more than a billion COVID-19 vaccine doses.

> “We have an exciting late-stage pipeline, and we expect to double the number of programs in Phase 3 by 2025 and launch up to 15 products in five years.”

Turning to the rest of our pipeline, positive clinical trial results across cancer, rare disease and infectious disease were shared during our annual R&D Day in September, when we announced our intent to launch up to 15 products in five years.

I will highlight a few notable 2023 milestones from across our 45 development programs.



The image above depicts Moderna's pipeline as a cell map, reflecting the new development candidates, Lyme, Mpox and Norovirus, added in 2023 to Moderna's infectious disease vaccines modality.

Respiratory Franchise

In 2023, we advanced our COVID, RSV and flu respiratory disease programs to positive Phase 3 data. We received U.S. FDA approval of our updated COVID-19 vaccine and filed a Biologics License Application (BLA) for our RSV vaccine. Additionally, our seasonal flu vaccine candidate met its primary endpoint in a Phase 3 trial, and consultations with regulators on a potential licensing package are ongoing.

Our combination vaccine candidates, which can also provide substantial public health benefits, address respiratory viruses associated with the largest disease burden in the category and are designed for higher compliance, increased uptake, consumer convenience and benefits to healthcare systems. Enrollment was completed in our combination trials for flu/COVID-19 (Phase 1/2), flu/RSV (Phase 1), and flu/COVID-19/RSV (Phase 1). We also recently initiated a Phase 3 trial of our combination vaccine against seasonal flu and COVID-19 with the intention to have a combination vaccine available as early as 2025.



> **"We were excited to see such a robust clinical benefit with our mRNA therapy, and to launch a new Phase 3 trial with non-small cell lung cancer patients in December."**

Latent Franchise

We continued to develop vaccines against six latent and other viruses with unmet or underserved needs, including cytomegalovirus (CMV), Epstein-Barr virus, herpes simplex virus, varicella zoster virus, norovirus and HIV. The pivotal Phase 3 study, CMVictory, of our CMV vaccine candidate fully enrolled with adults to evaluate the efficacy, safety and immunogenicity of the vaccine in the prevention of primary infection in women of childbearing age. The Phase 3 study is event-based but given the number of cases we have already seen, we could have CMV Phase 3 data in 2024. CMV is the most common infectious cause of birth defects in the U.S. and CMV has been designated a top priority in new vaccine development by the U.S. National Academy of Medicine for more than two decades.

Oncology Franchise

In 2023, we reported additional data from our Phase 2b trial evaluating our individualized neoantigen therapy (INT) in combination with Merck's KEYTRUDA® in melanoma patients compared to KEYTRUDA alone. The treatment continued to show significant and clinically meaningful improvement in recurrence-free survival and reduced the risk of recurrence or death by 49 percent. These data, with a median follow-up of approximately three years, demonstrate the durability of the therapy.

We were excited to see such a robust clinical benefit with our mRNA therapy, and to launch a new Phase 3 trial with non-small cell lung cancer patients in December. To support this continued progress, we have been investing in building a factory in Marlborough, Massachusetts, and in building out our people capability, which will enable the commercial launch for INT.

Rare Disease Franchise

Our rare disease portfolio, which includes therapies targeting methylmalonic acidemia (MMA), propionic acidemia (PA), glycogen storage disease and Phenylketonuria, continued to show promise. The Phase 1/2 trial for our MMA therapy candidate has dosed 11 participants with a total of 221 doses administered and all participants have opted into the Open-Label Extension study. A global Phase 1/2 trial for our PA candidate, which is our most advanced rare disease program, is enrolling patients in the dose confirmation arm, and most patients who have completed the treatment period of the main study have opted to enter a long-term extension study.

> “Staying true to our Mission, we will also continue to invest in science to expand the field of mRNA medicine into new frontiers.”

Focusing on Execution

As you can see, we have built significant momentum across our business and our pipeline. Across our respiratory, latent, oncology and rare franchises, we are aiming to launch up to 15 new products over the next five years. We are excited by the near future and focused on execution to deliver for patients.

Staying true to our Mission, we will also continue to invest in science to expand the field of mRNA medicine into new frontiers. For example, in partnership with Vertex, we are advancing an investigational inhaled mRNA therapy in the lung to treat the underlying cause of cystic fibrosis, which we expect to read out in 2024.

Over the same five-year period, we expect to advance many new candidate medicines into clinical trials across established and new modalities. To do this, we will continue to lead with our Values, our Mindsets and a deep sense of purpose in everything we do.

Acting Responsibly

Our commitment to corporate social responsibility remains strong, as evidenced by the publication of our second annual ESG Report in June. As a company, we care deeply about our patients, our employees, the environment and our communities, and we recognize that we have an opportunity to change medicine for all. We will continue to engage, listen and understand what our stakeholders expect from us as a sustainable, responsible business and leader in mRNA medicines.

This leadership is made possible by our people, who are the driving force behind our progress and our culture. I am proud of our team and award-winning culture, which earned Moderna recognition from *Science* as a top employer for the ninth consecutive year, from *BioSpace* as the #1 large employer in its Best Places to Work report for the third year in a row, and from the Human Rights Campaign Foundation as an Equality 100 company for the first time in 2023.


Cradles to Crayons
Volunteer Week

"This leadership is made possible by our people, who are the driving force behind our progress and our culture."

Looking Ahead

Our focus for 2024 and 2025 is to drive sales growth *and* profitability. To achieve that, we are focusing on three priorities.

Priority one is commercial execution. Our recent market share gain in the U.S. demonstrates that we can compete with large established players. We expect COVID sales to stabilize in a fully endemic market, and we will build on our current momentum to grow our market share for Spikevax in 2024.

To support this, we made the decision at the end of 2023 to flatten our commercial organization to help us accelerate decisions and increase customer understanding as we prepare for multiple product launches. With the expected launch of our RSV vaccine candidate in 2024, and potential launch of our flu/COVID combination vaccine as early as 2025, we believe Moderna will experience sales growth in 2025.

Priority two is disciplined investment. We will continue to review our manufacturing costs, product pipeline, and deliver efficiencies. Our upcoming respiratory product launches in 2024 and 2025 will also achieve efficiencies from a growing pipeline.

Priority three is executing on our late-stage pipeline to drive organic sales growth. We have an exciting late-stage pipeline, and we expect to double the number of programs in Phase 3 by 2025 and launch up to 15 products in five years. Up to four of those launches could come by 2025.

With these priorities, we are completing our strategy to accelerate the growth of our business, a journey we have been on since mid-2021. We expect to break even in 2026, as revenue grows and late-stage R&D costs recede, when the current large Phase 3 clinical trials wind down and result in many potential new product launches.

Along the way, we will continue to invest in our people—the changemakers who help us maximize our impact on human health. I am so grateful for their dedication to our Mission and their relentless work. I am also thankful to all the people and organizations that partner with us on this journey to advance our Mission to deliver the greatest possible impact to people through mRNA medicines.

Thank you all for your ongoing trust and support as we work to deliver value to all our stakeholders, and bring mRNA medicines to the world.

We are excited about 2024. This is just the beginning...

Warmest regards,



Stéphane Bancel
Chief Executive Officer

Advancing mRNA respiratory vaccines

We are well-prepared for the launch of our second respiratory vaccine, RSV (mRNA-1345), which will build upon the success of our commercial efforts in the fall COVID-19 market.

We are encouraged by early indications of widespread consumer awareness and established demand in the RSV market, which we will enter with a strong competitive profile with robust efficacy data, a well-established safety and tolerability profile, and as the only pre-filled syringe (PFS) product available at the time of launch.

With a substantial number of U.S. RSV vaccines given to date in the pharmacy setting, PFS presentation offers ease of use, time savings and the potential to reduce medical errors. Given the labor shortage in the retail pharmacy channel, we anticipate our PFS presentation will be welcomed by pharmacists during the busy respiratory vaccine season, where pharmacists need, in addition to their regular tasks, to administer flu, COVID and RSV vaccines.

We have filed for regulatory approvals of our vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults ages 60 years or older. The regulatory applications are based on positive data from the pivotal ConquerRSV study, a randomized, double-blind, placebo-controlled study of approximately 37,000 adults, 60 years or older. The trial met both its primary efficacy endpoints, with a vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-LRTD as defined by two or more symptoms, and a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078) against RSV-LRTD defined by three or more symptoms. Most solicited adverse reactions were mild to moderate, and no cases of Guillain-Barre Syndrome (GBS) have been reported with mRNA-1345 in the Phase 3 RSV trial. These data were published in the *New England Journal of Medicine* in December 2023.

Follow-up data from a Phase 3 RSV study with a median follow-up duration of 8.6 months, with a range of 15 days to 530 days, and including subjects from the Northern and Southern Hemispheres was recently presented at the RSVVW'24 conference. In this supplemental analysis, mRNA-1345 maintained durable efficacy, with sustained VE of 63.3% (95.88% CI: 48.7%, 73.7%) against RSV-LRTD including two or more symptoms. VE was 74.6% (95% CI, 50.7-86.9) against RSV-LRTD with ≥2 symptoms, including shortness of breath and 63.0% (95% CI, 37.3-78.2) against RSV-LRTD including three of more symptoms. The stringent statistical criterion of the study, a lower bound on the 95% CI of >20%, continued to be met for both endpoints.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover within a week or two, but infants and older adults, who are more vulnerable, can develop severe complications leading to hospitalization. The rising global incidence of severe RSV in older adults has highlighted the urgent need for better prevention strategies.



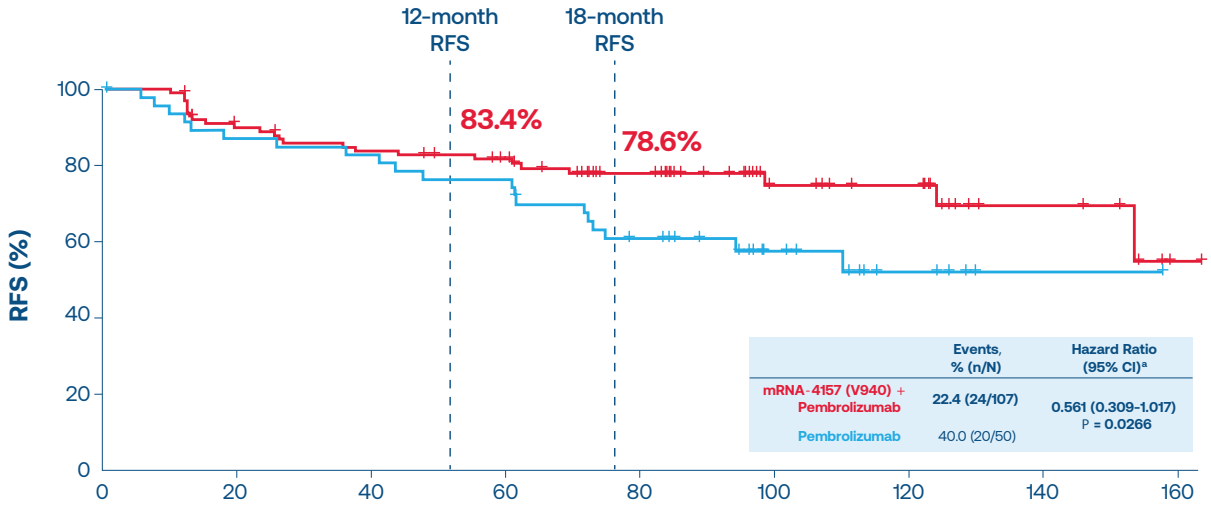
A new frontier in cancer care

We, along with our partner Merck, are pioneering a new frontier in the fight against cancer by researching an mRNA-based investigational individualized neoantigen therapy (INT) with the goal of targeting each patient's unique cancer cells.

Our INT, mRNA-4157, marks an advancement at the intersection of immunology and cancer biology, leveraging a combination of technological, digital, and biological innovations. At its heart, this approach is patient-focused, utilizing next-generation sequencing to identify tumor-specific mutations from a patient's blood sample. These mutations are analyzed by a proprietary algorithm to select up to 34 neoantigens, which are then used to create an individualized mRNA treatment aimed at training the patient's immune system to recognize and fight cancer cells. This entire process can be achieved within about six weeks.

We made great strides in our INT program in 2023. We announced that in our Phase 2 study, mRNA-4157, in combination with pembrolizumab, demonstrated a clinically meaningful improvement in recurrence-free survival and distant metastasis-free survival compared to standard of care in high-risk resected melanoma. We saw a 49% reduction in the risk of recurrence or death and a 62% reduction in the risk of distant metastasis or death compared to pembrolizumab alone with a median of three years of follow-up, and a Phase 3 pivotal study has begun enrolling.

mRNA-4157 (V940) in combination with Pembrolizumab reduced the risk of recurrence or death by 44% compared to Pembrolizumab alone



Time from first dose of Pembrolizumab (weeks)

Number at risk									
mRNA-4157 (V940) + Pembrolizumab	107	92	85	73	49	24	20	8	1
Pembrolizumab	50	42	40	37	28	13	6	1	0

1. Khattak A, et al. Presented at the American Association for Cancer Research® (AACR) Annual Meeting; April 14-19, 2023; Orlando, FL, USA. Oral presentation CT001.
2. Khattak A, et al. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL, USA. Oral presentation CI, confidence interval; mRNA, messenger RNA; RFS, recurrence-free survival.aThe hazard ratio and 95% CI for mRNA-4157 (V940) plus pembrolizumab versus pembrolizumab is estimated using a Cox proportional hazards model with treatment group as a covariate, stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization. The P value is based on a 1-sided log-rank test stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization.

We have also initiated a Phase 3 trial in non-small cell lung cancer that is actively enrolling and plan to expand the development program to additional tumor types. To supply product to these trials and in preparation for the future, we announced that we are building a manufacturing site in Marlborough, MA as a commercial INT manufacturing facility.

We believe an individualized neoantigen therapy can be a catalyst for innovation and drive us toward the next frontier of cancer care. By harnessing the power of mRNA, we hope to bring this potential therapy to the patients who need it as quickly as possible.



Manufacturing site in Marlborough, MA.

Pipeline

Below is Moderna's pipeline as of February 22, 2024.

	Program Indication	ID #	Preclinical Development	Phase 1
RESPIRATORY VACCINES				
ADULTS	***COVID-19 vaccine***	*Spikevax® (mRNA-1273)*		
		mRNA-1283		
	Flu vaccine	*mRNA-1010*		
		mRNA-1020		
		mRNA-1030		
		mRNA-1011		
		mRNA-1012		
	Older adults RSV vaccine	*mRNA-1345*		
	Flu + COVID vaccine	*mRNA-1083*		
	Flu + COVID + RSV vaccine	*mRNA-1230*		
	Flu + RSV vaccine	*mRNA-1045*		
	Endemic HCoV vaccine	*mRNA-1287*		
	Pandemic Flu	*mRNA-1018*		
	RSV + hMPV vaccine	*mRNA-1365*		
ADOLESCENTS AND PEDIATRICS	***COVID-19 vaccine (adolescents)***	*mRNA-1273.815*	TeenCOVE	
	COVID-19 vaccine (pediatrics)	*mRNA-1273.815*	KidCOVE	
	Pediatric RSV vaccine	*mRNA-1345*		

Abbreviations:

BARDA: Biomedical Advanced Research and Development Authority
CMV: cytomegalovirus
CN-1: Crigler-Najjar syndrome type 1
EBV: Epstein-Barr Virus
GSD1a: glycogen storage disease type 1a
HCoV: human coronavirus
HIV: human immunodeficiency virus
hMPV: human metapneumovirus
HSV: herpes simplex virus
IAVI: International AIDS Vaccine Initiative
IL-23: interleukin 23
IL-36 γ: interleukin 36 gamma

RESPIRATORY VACCINES



ILCM: Institute for Life Changing Medicine
MMA: methylmalonic acidemia
NIH: National Institutes of Health

NSCLC: non-small cell lung cancer
OTC: ornithine transcarbamylase deficiency

PA: propionic acidemia
PKU: phenylketonuria

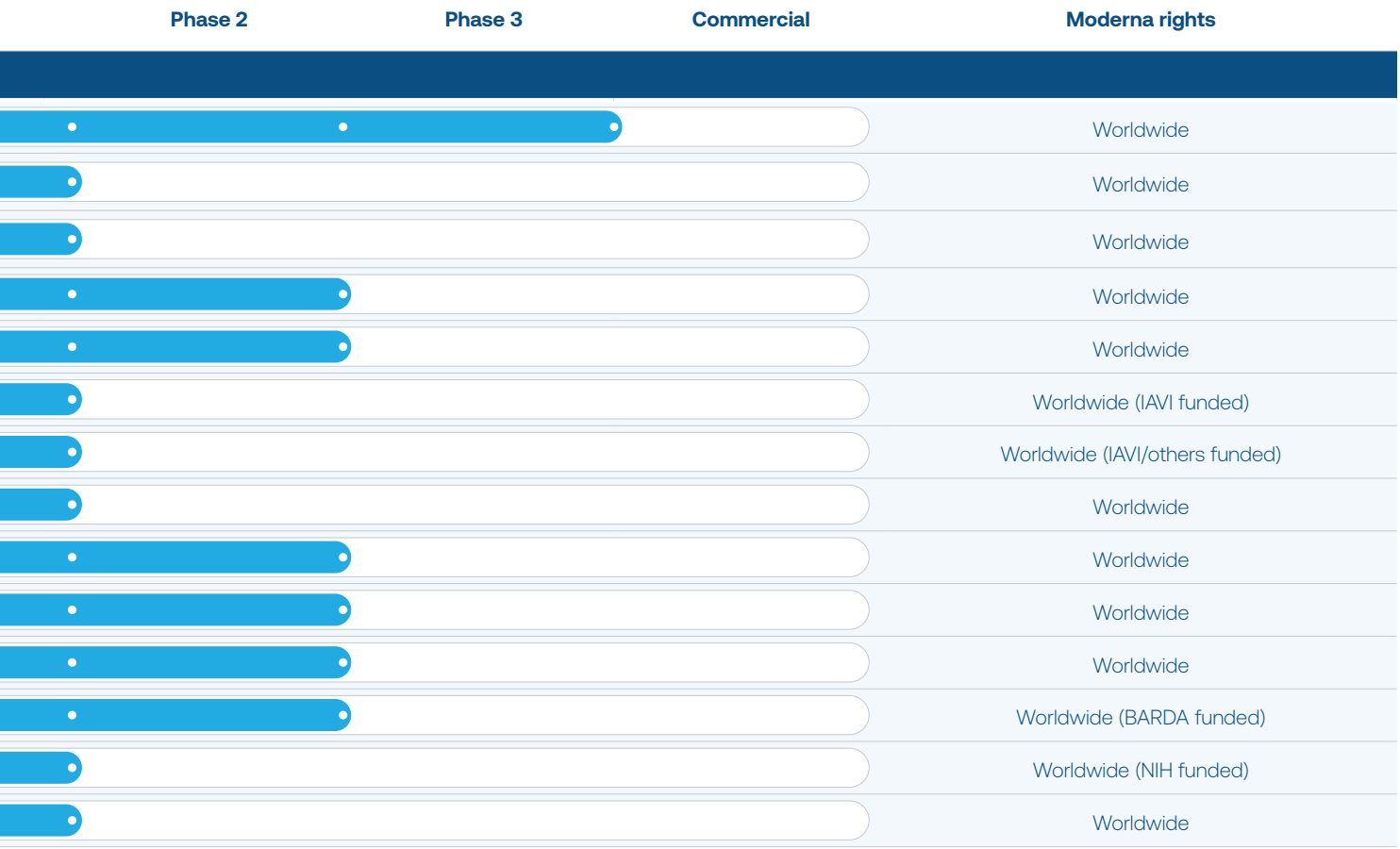
RSV: respiratory syncytial virus
VZV: varicella-zoster virus

	Program Indication	ID #	Preclinical Development	Phase 1
LATENT VACCINES & OTHER VACCINES				
LATENT VACCINES	***CMV vaccine***	*mRNA-1647*		
	EBV vaccine *(to prevent infectious mononucleosis)*	*mRNA-1189*		
	EBV vaccine *(to address EBV sequelae)*	*mRNA-1195*		
	HSV vaccine	*mRNA-1608*		
	VZV vaccine	*mRNA-1468*		
	HIV vaccines	*mRNA-1644*		
		mRNA-1574		
ENTERIC	***Norovirus vaccines***	*mRNA-1403*		
		mRNA-1405		
BACTERIAL	***Lyme vaccines***	*mRNA-1975*		
		mRNA-1982		
PUBLIC HEALTH VACCINES	***Zika vaccine***	*mRNA-1893*		
	Nipah vaccine	*mRNA-1215*		
	Mpox vaccine	*mRNA-1769*		

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LATENT & OTHER VACCINES



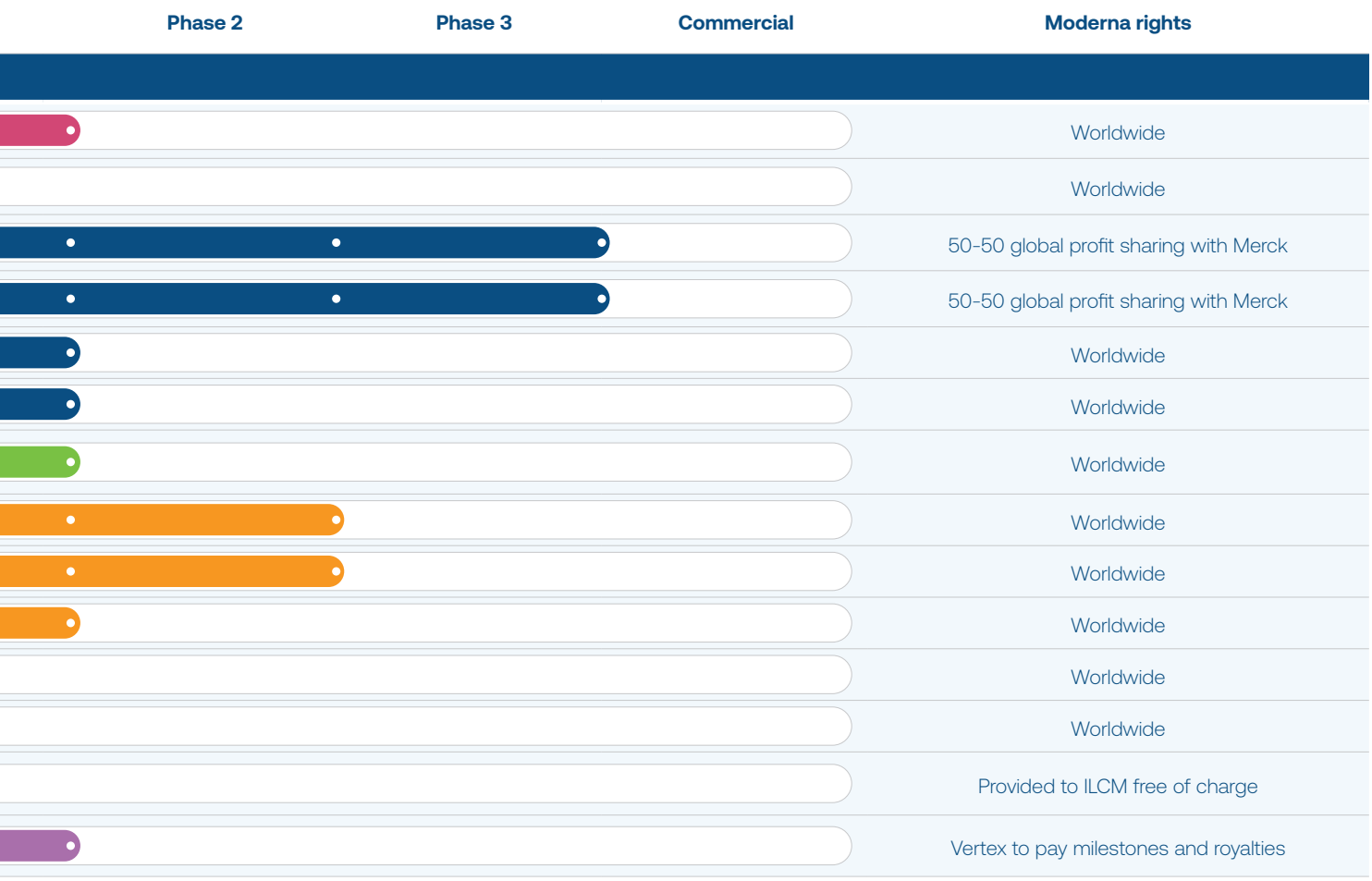
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	Program Indication	ID #	Preclinical Development	Phase 1
THERAPEUTICS				
SYSTEMIC SECRETED & CELL SURFACE THERAPEUTICS	***Relaxin*** *Heart failure*	*mRNA-0184*		
	PD-L1 *Autoimmune hepatitis*	*mRNA-6981*		
CANCER VACCINES & THERAPEUTICS	***Individualized neoantigen therapy (INT)*** *–adjuvant melanoma*	*mRNA-4157*		
	Individualized neoantigen therapy (INT) *–adjuvant NSCLC*	*mRNA-4157*		
	KRAS vaccine	*mRNA-5671*		
	Checkpoint vaccine	*mRNA-4359*		
INTRATUMORAL IMMUNO-ONCOLOGY	***OX40L/IL-23/IL-36γ (Triplet)*** *Solid tumors/lymphoma*	*mRNA-2752*		
RARE DISEASE INTRACELLULAR THERAPEUTICS	***PA***	*mRNA-3927*		
	MMA	*mRNA-3705*		
	GSD1a	*mRNA-3745*		
	OTC	*mRNA-3139*		
	PKU	*mRNA-3210*		
	CN-1	*mRNA-3351*		
INHALED PULMONARY THERAPEUTICS	***Cystic fibrosis***	*mRNA-3692 / VX-522*		

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Building our team

Creating a Unique Organization

We continue to focus on the elements of our culture to create an environment where everyone can have an impact. Our Mission, Values and Mindsets support our ways of working and unite our people in our shared goal to change how medicines are made and delivered.

As part of our efforts to scale our culture, we introduced the concept of our 'People Platform' in 2023. This concept involves regularly reviewing the programs we provide for our employees, the systems that underpin them, and the data and insights they generate. We aim to ensure that every employee, regardless of their location or level, experiences the same employee journey and that our culture is embedded throughout this journey.

We emphasize learning and development. In 2023, we focused on upskilling our teams on topics such as artificial intelligence (AI) and how AI and machine learning can help ensure we are digitizing everywhere.

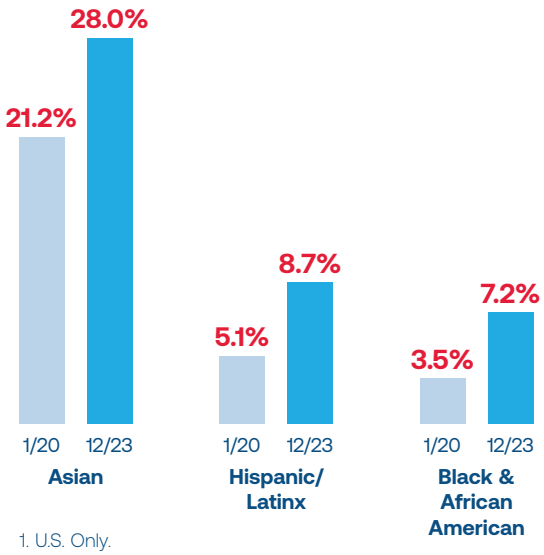
Leading with Belonging

In addition to system-level improvements, we focus heavily on the individual. Our strategy for diversity and inclusion starts with belonging. We believe that employees can only thrive and innovate when they feel they belong and can be their authentic selves.

Our workforce demographics show that 49 percent of our employees are women, with 39 percent female representation in executive roles as of December 2023. Although this represents a slight decline from the prior year, we are proud of these figures, and have made significant strides in our race and ethnicity demographics by focusing on our early talent pipeline. Of our inaugural group of MBA interns, 43 percent identified with races or ethnicities that are underrepresented.

One achievement we take immense pride in is our commitment to pay equity. We ensure equal pay for equal work, a commitment we have upheld for the second year running.

Race & Ethnicity[1]



1. U.S. Only.

We also care deeply about our employees' well-being and understand that each employee has unique needs that change over time. Therefore, we provide programs that focus on meeting employees where they are and that are tailored to their needs. Recently introduced programs include enhanced mental health and life insurance benefits.

Our focus remains on creating an inclusive environment where every individual can thrive and contribute to our mission. We are committed to continuous learning and improvement in this area, always striving to do better for our people.

Celebrating Our Culture

Moderna ranked 9th among biopharmaceutical companies in this year's *Science* survey. Marking our ninth consecutive year on this list, we were recognized for our commitment to innovative leadership, respect for employees and corporate social responsibility.

Additionally, *BioSpace* named Moderna the number one large employer in its Best Places to Work report for the third year in a row. We were also recognized by the Human Rights Campaign Foundation as an Equality 100 company for the first time in 2023—a proud moment for Moderna as we continue to build a culture of belonging.



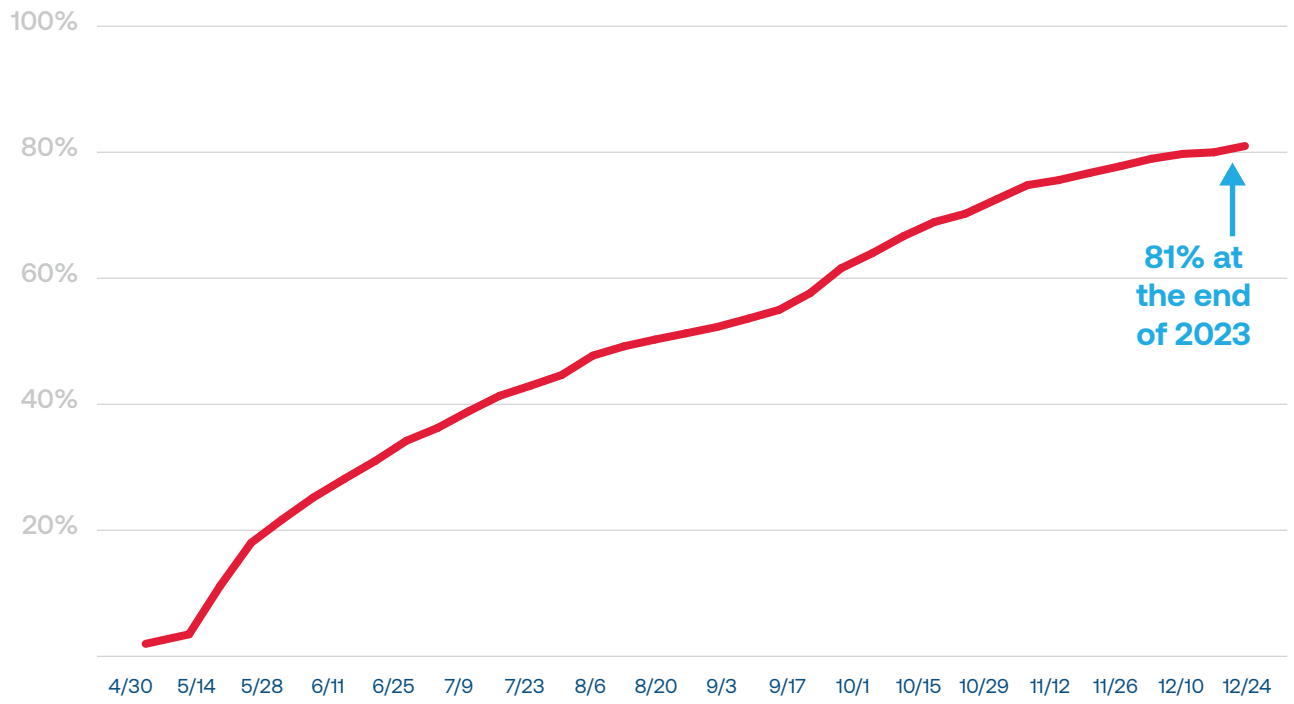
"We believe that employees can only thrive and innovate when they feel they belong and can be their authentic selves."

Digitizing everywhere

In 2021, when we developed the Moderna Mindsets to help encode our culture, we articulated our commitment to digitizing everywhere possible. Digital technology has been part of our programs since our early days and we have built our own AI models for protein and mRNA engineering, assay data analyses, regulatory interaction and many other use cases. As a recent example, we used AI to develop an internal scheduling algorithm to optimize our manufacturing process for our investigational INT program to account for manufacturing capacity and target dosing dates for all active patients in our Phase 3 trials targeting melanoma and non-small cell lung cancer globally, taking a highly patient-centric approach.

We are well-positioned to scale our manufacturing and our business overall using AI because we are a platform company. AI training is required of all Moderna team members and we facilitate this training at a corporate level through our AI Academy. We have challenged everyone across all our business functions to incorporate AI into their everyday workflows. Our AI implementation is accelerating throughout Moderna, where our secure large language model usage has grown rapidly to approximately 81 percent of our employee base since its introduction in May 2023.

Percentage of Moderna employees who are active mChat users



Responsibility

We are guided by our unwavering belief that our mRNA platform can solve the world's greatest health challenges—from diseases impacting millions to medicines personalized to the individual level. We also operate with a deep sense of purpose and care for our patients, our employees, the environment, and our communities. We underscored our commitment to responsible corporate citizenship through the publication of our second annual ESG Report in June 2023.

Prioritizing Inclusive Research

In 2023, we remained steadfast in our commitment to inclusive research, developing mRNA-based investigational therapies and vaccines that are equitable for all. Recognizing the importance of diversity for scientific excellence, we design our clinical trials to reflect the global community, particularly those disproportionately affected by diseases. We continue to make significant strides in including medically underserved communities and diverse populations and have set a standard in our healthy volunteer clinical trials with at least 37 percent of trial participants from global ethnic majority groups, at least half being female, and representation across all age groups. We are proud to not just meet industry expectations but set and exceed them in every demographic category.

To sustain our drive toward inclusive research, we concentrate our efforts around three pillars: increasing awareness, bringing trials into communities, and providing flexible participation options. This approach has led to increased enrollment, retention, and participant satisfaction. At its core, our commitment to innovative and inclusive clinical trials helps to ensure that potential medicines of tomorrow are accessible to all.

Focusing on Global Public Health

In 2023, we continued to leverage our mRNA platform to address potential global public health threats and build pandemic preparedness, addressing priority pathogens that represent high disease burden, especially in low- and middle-income countries.



Our mRNA Access global partners[1]:



1. non-exhaustive

Moderna's global public health portfolio, launched in 2022, continues to evolve, with advanced clinical trials against diseases such as Zika, Mpox, HIV, and Nipah. Our focus has expanded to include other respiratory threats like pandemic influenza, with our mRNA-1018 program making strides in clinical testing. Through our mRNA Access program, we have increased collaborations and opened preclinical production capabilities to more academic institutions worldwide, decentralizing the research and development of mRNA vaccines. We are also developing new manufacturing sites in Australia, Canada and the U.K. to enhance our ability to swiftly respond to potential regional and global pandemic outbreaks.

In October 2023, we entered into a strategic partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) with the goal of harnessing Moderna's mRNA platform to accelerate the development of vaccines against viral disease outbreaks that threaten global health. The work undertaken as part of this partnership could expand the infectious disease targets for mRNA vaccine technology and strengthen pandemic preparedness and public health efforts in alignment with the 100 Days Mission, a global goal to compress vaccine development timelines to 100 days.

Building the Moderna Charitable Foundation

The Moderna Charitable Foundation continues to make a positive impact in our communities locally and globally. Through philanthropic giving, employee gift matching, and humanitarian relief, the Moderna Foundation supported nonprofit organizations with $8.5 million in grants in 2023, with a significant focus on improving health systems in sub-Saharan Africa. Partnerships with organizations such as Science Club for Girls, CDC Foundation, Imperial College London, and Amref Health Africa further advance the Foundation's mission to promote public health, advance scientific education, and advocate for diversity and inclusion.

Giving Back to the Community

Our commitment to serve the communities where we live and work has always been part of our identity, and we constantly strive to extend our impact on society. Each year between Giving Tuesday and International Volunteer Day, we organize a company-wide Volunteer Week. 2023 marked our fifth annual Volunteer Week, and hundreds of Moderna team members participated in organized activities across 15 countries, up from six in 2022, to make a substantial impact with community partners around the world.

All our team members receive eight hours of paid time off each year to dedicate toward volunteering, and our Dollars for Doers program matches additional volunteer time at a specific hourly rate. Additionally, the Moderna Charitable Foundation matches monetary donations that employees have made to qualified charitable organizations. In 2023, our collective efforts supported more than 2,000 nonprofits around the world, with 70 percent of our workforce engaging in giving and/or volunteering.

Protecting the Environment

In 2023, we advanced our environmental sustainability efforts underlined by a strategy focused on Sustainability by Design, Natural Resource Conservation, and Value Chain Decarbonization. We have launched initiatives like a climate risk and scenario analysis, increased public greenhouse gases (GHG) emissions disclosures, and incorporated energy-saving technologies in new constructions. We are also working to reduce Scope 3 emissions with suppliers and promoting green employee transport. As Moderna prepares for 2024, we aim to further integrate climate risk management, validate our GHG emissions reduction roadmap by Science Based Targets initiative (SBTi), and enhance energy, emissions, and waste programs, reinforcing our commitment to environmental stewardship as part of our healthcare mission.



Leadership

Executive Committee



In order left to right

Stephen Hoge, MD | President

Stéphane Bancel | Chief Executive Officer

Tracey Franklin | Chief Human Resources Officer

Kate Cronin | Chief Brand Officer

Jerh Collins, PhD | Chief Technical Operations and Quality Officer

Shannon Thyme Klinger | Chief Legal Officer and Corporate Secretary

Brad Miller | Chief Information Officer

Jamey Mock | Chief Financial Officer

Board of Directors

Noubar Afeyan, PhD | Co-founder and Chairman, Moderna; Chief Executive Officer, Flagship Pioneering

Stéphane Bancel | Chief Executive Officer, Moderna

Stephen Berenson | Managing Partner, Flagship Pioneering

Sandra Horning, MD | Former Chief Medical Officer and Global Head of Product Development, Roche

Robert Langer, ScD | Academic Co-Founder, Moderna; David H. Koch Institute Professor, MIT

Elizabeth Nabel, MD | Former President, Brigham Health

François Nader, MD | Former President, CEO and Executive Director, NPS Pharmaceuticals

Paul Sagan | Catalyst Advisor, General Catalyst

Elizabeth Tallett | Former Principal, Hunter Partners

In Memoriam, **Henri Termeer** | Retired Chairman, President and CEO of Genzyme

Awards and recognition highlights

BioSpace Best Places to Work
Ranked no. 1 large company on 2024 list

Boston Consulting Group's 50 Most Innovative Report
Ranked no. 6 on 2023 list

Deloitte's Technology Fast 500 List
Ranked no. 4 on the 2023 list

Disability Equality Index's Best Places to Work
Scored 100/100 in 2023

Edison Gold Award
Awarded in 2023 for Advanced Drug Delivery: COVID-19 Vaccine

Financial Times Americas' Fastest Growing Companies
Ranked no. 5 in 2023

Fortune 500 List
Ranked no. 211 on the 2023 list

Fortune's World's Most Admired Companies
Ranked no. 37 on 2024 list

Great Place to Work
Certified in U.S. in 2023

Human Rights Campaign Foundation's Corporate Equality Index
Scored 100/100 in 2023

Science Careers' Top Employers
Ranked for nine consecutive years; no. 9 on 2023 list

Vaccine Industry Excellence Award
Awarded for Best COVID Vaccine in 2023



Consolidated Balance Sheets

(in millions)	December 31, 2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,907	$ 3,205
Investments	5,697	6,697
Accounts receivable, net	892	1,385
Inventory	202	949
Prepaid expenses and other current assets	627	1,195
Total current assets	**10,325**	**13,431**
Investments, non-current	4,677	8,318
Property, plant and equipment, net	1,945	2,018
Right-of-use assets, operating leases	713	121
Deferred tax assets	81	982
Other non-current assets	685	988
Total assets	**$ 18,426**	**$ 25,858**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 520	$ 487
Accrued liabilities	1,798	2,101
Deferred revenue	568	2,038
Income taxes payable	63	48
Other current liabilities	66	249
Total current liabilities	**3,015**	**4,923**
Deferred revenue, non-current	83	673
Operating lease liabilities, non-current	643	92
Financing lease liabilities, non-current	575	912
Other non-current liabilities	256	135
Total liabilities	**4,572**	**6,735**
Stockholders' equity:		
Additional paid-in capital	371	1,173
Accumulated other comprehensive loss	(123)	(370)
Retained earnings	13,606	18,320
Total stockholders' equity	**13,854**	**19,123**
Total liabilities and stockholders' equity	**$ 18,426**	**$ 25,858**

The Consolidated Balance Sheets have been derived from our audited consolidated financial statements included in Moderna's Annual Report on Form 10-K.

Consolidated Statements of Operations

(in millions, except per share data)	Years Ended December 31, 2023	2022
Revenue:		
Net product sales	$ 6,671	$ 18,435
Other revenue[1]	177	828
Total revenue	**6,848**	**19,263**
Operating expenses:		
Cost of sales	4,693	5,416
Research and development	4,845	3,295
Selling, general and administrative	1,549	1,132
Total operating expenses	**11,087**	**9,843**
(Loss) income from operations	(4,239)	9,420
Interest income	421	200
Other expense, net	(124)	(45)
(Loss) income before income taxes	(3,942)	9,575
(Benefit from) provision for income taxes	772	1,213
Net (loss) income	**$ (4,714)**	**$ 8,362**
(Loss) earnings per share:		
Basic	$ (12.33)	$ 21.26
Diluted	$ (12.33)	$ 20.12
Weighted average common shares used in calculation of (loss) earnings per share:		
Basic	382	394
Diluted	382	416

1. Includes grant revenue and collaboration revenue

The Consolidated Statements of Operations have been derived from our audited consolidated financial statements included in Moderna's Annual Report on Form 10-K.

Consolidated Statements of Cash Flows

(in millions)	Years Ended December 31, 2023	2022
Operating activities		
Net (loss) income	$ (4,714)	$ 8,362
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation	305	226
Depreciation and amortization	621	348
Amortization/accretion of investments	(61)	31
Loss on equity investments, net	35	—
Deferred income taxes	828	(559)
Other non-cash items	7	28
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	493	1,790
Prepaid expenses and other assets	974	(1,699)
Inventory	747	492
Right-of-use assets, operating leases	(605)	21
Accounts payable	13	240
Accrued liabilities	(340)	612
Deferred revenue	(2,060)	(4,157)
Income taxes payable	15	(828)
Operating lease liabilities	551	(14)
Other liabilities	73	88
Net cash (used in) provided by operating activities	**(3,118)**	**4,981**
Investing activities		
Purchases of marketable securities	(3,760)	(11,435)
Proceeds from maturities of marketable securities	5,575	3,151
Proceeds from sales of marketable securities	3,206	3,548
Purchases of property, plant and equipment	(707)	(400)
Acquisition of business, net of cash acquired	(85)	—
Investment in convertible notes and equity securities	(23)	(40)
Net cash provided by (used in) investing activities	**4,206**	**(5,176)**
Financing activities		
Proceeds from issuance of common stock through equity plans	46	65
Repurchase of common stock, including excise tax	(1,153)	(3,329)
Changes in financing lease liabilities	(270)	(184)
Net cash used in financing activities	**(1,377)**	**(3,448)**
Net decrease in cash, cash equivalents and restricted cash	(289)	(3,643)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	**$ 2,928**	**$ 3,217**

The Consolidated Statements of Cash Flows have been derived from our audited consolidated financial statements included in Moderna's Annual Report on Form 10-K.

Forward-Looking Statements Disclaimer

This annual report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the potential of Moderna's mRNA platform; Moderna's ability to bring medicines to market; Moderna's expectation that its COVID-19 franchise will be profitable for 2024 and beyond; Moderna's ability to compete in the commercial market and future market share; the potential 2024 launch of Moderna's RSV vaccine for adults with a potentially best-in-class profile; our ability to compete in the RSV market, and the advantages of our PFS presentation; the safety and tolerability profile of Moderna's mRNA vaccine technology; Moderna's intent to launch up to 15 products in five years; the potential for approval of Moderna's seasonal flu vaccine candidate and the timing for that approval; the anticipated benefits of combination vaccines, and Moderna's intent to have a flu/COVID combination vaccine available as early as 2025; the clinical benefit observed with Moderna's mRNA cancer therapy; Moderna's plans to expand INT to additional tumor types; Moderna's construction of a factory to support INT; the promise of Moderna's rare disease franchise; the expected read out in 2024 for Moderna's mRNA therapy for cystic fibrosis and potential readout for CMV; Moderna's ability to scale its manufacturing and business overall using AI; Moderna's expectation to be in sales growth by 2025 and to break even in 2026; Moderna's expectation to double the number of programs in Phase 3 by 2025; and the timing and scale for Moderna's planned investments in research and development. The forward-looking statements in this annual report are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission (SEC), and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this annual report in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this annual report.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _ to _
Commission File Number: 001-38753



Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-3467528**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
200 Technology Square Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	(Zip Code)

(617) 714-6500
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**MRNA**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☑ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☑ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☑ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. **Yes** ☑ **No** ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☑

As of June 30, 2023, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $40.2 billion based on the closing sale price on that date of $121.50. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of February 16, 2024, there were 382,073,208 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to its 2024 Annual Meeting of Stockholders to be filed hereafter are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

Table of Contents

		Page
PART I.		
Item 1.	Business	7
Item 1A.	Risk Factors	47
Item 1B.	Unresolved Staff Comments	80
Item 1C.	Cybersecurity	80
Item 2.	Properties	81
Item 3.	Legal Proceedings	81
Item 4.	Mine Safety Disclosures	82
PART II.		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	83
Item 6.	[Reserved]	84
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	85
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	100
Item 8.	Financial Statements and Supplementary Data	102
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	141
Item 9A.	Controls and Procedures	142
Item 9B.	Other Information	144
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	144
PART III.		
Item 10.	Directors, Executive Officers and Corporate Governance	145
Item 11.	Executive Compensation	145
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	145
Item 13.	Certain Relationships and Related Transactions, and Director Independence	145
Item 14.	Principal Accountant Fees and Services	145
PART IV.		
Item 15.	Exhibits, Financial Statement Schedules	146
Item 16.	Form 10-K Summary	149
Signatures		150

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- Evolving dynamics in the market for COVID-19 vaccines are likely to impact our financial results, which are likely to result in lower product revenues in 2024 than we have experienced in recent years;
- We may encounter difficulties producing or shipping our products consistent with our projections or future contractual commitments;
- We have limited sales, distribution and marketing experience and may be unable to effectively establish such capabilities or supplement our capabilities by entering into agreements with third parties;
- The pharmaceutical market is intensely competitive, and we may not compete effectively in the market for existing products, new treatment methods and new technologies;
- We may be unsuccessful or delayed in updating our COVID-19 vaccine to protect against future variants of the SARS-CoV-2 virus, and updated versions of our COVID-19 vaccine may not protect against such variants;
- The commercial success of our products will depend on the degree of market acceptance by physicians, patients, third-party payors and others in the medical community;
- Sales of pharmaceutical products depend on the availability and extent of reimbursement from third-party payors, and we may be adversely impacted by changes to such reimbursement policies or rules;
- Preclinical development is lengthy and uncertain, especially for mRNA medicines, and our preclinical programs or product candidates may be delayed or terminated;
- Clinical development is lengthy and uncertain, and our clinical programs may be delayed or terminated, or may be more costly to conduct than we anticipate;
- If we cannot obtain, or are delayed in obtaining, required regulatory approvals, we will be unable to commercialize, or will be delayed in commercializing, product candidates we may develop;
- Our mRNA products and product candidates are based on novel technologies and are complex and difficult to manufacture. We or our third-party manufacturers may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping for any of our products;
- As we grow as a commercial company and our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We rely on third-party service providers, all of whom have inherent risks in their operations;
- We are subject to operational risks associated with the physical and digital infrastructure at our manufacturing facilities and those of our external service providers;
- Our individualized neoantigen therapy (INT) product candidates are uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in producing INT;
- We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our products and product candidates;
- We have entered into, and in the future may enter into, strategic alliances with third parties for the development and commercialization of products and product candidates. If these strategic alliances are not successful, our business could be adversely affected;
- We may seek to establish additional strategic alliances and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products;
- We may be unable to obtain and enforce patent protection for our discoveries and the intellectual property rights therein, or protect the confidentiality of our trade secrets;
- Uncertainty over intellectual property in the pharmaceutical and biotechnology industry has been the source of litigation and other disputes, which is inherently costly and unpredictable and can have adverse financial and freedom-to-operate consequences;
- We incurred net losses in 2023 and we are likely to incur losses again in the future; we have a limited history of recognizing revenue from product sales and may be unable to achieve long-term sustainable profitability;
- We may encounter difficulties in managing the development and expansion of our company;
- Our internal computer systems and physical premises, or those of third parties with which we share sensitive data or information, may fail or suffer security breaches, including from cybersecurity incidents, which could materially disrupt our product development programs and manufacturing operations; and
- The price of our common stock has been volatile, which could result in substantial losses for stockholders.

You should consider carefully the risks and uncertainties described below, in the section entitled "Risk Factors" and the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, before you decide whether to purchase our common stock. The risks described above are not the only risks that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expectations regarding the future profitability of our COVID-19 vaccine franchise, as well as our ability to grow and maintain market share;
- our expectations regarding the evolution of the endemic, commercial COVID-19 vaccine market and future demand for COVID-19 vaccines;
- our expectations regarding sales of our COVID-19 vaccine in 2024 and beyond;
- our ability to continue to develop variant-specific versions of our COVID-19 vaccine that are able to effectively combat COVID-19 as the SARS-CoV-2 virus continues to evolve;
- the potential launch, following regulatory approvals, of our respiratory syncytial virus (RSV) vaccine for adults in the first half of 2024, as well as additional respiratory product launches in 2024 and 2025;
- the durability of our individualized neoantigen therapy (INT) candidate, the ability of our INT candidate to address different types of cancer, our Phase 3 clinical trials in adjuvant melanoma and non-small cell lung cancer (NSCLC) and our plans to rapidly expand to additional tumor types;
- our goal to launch up to 15 new products over the next five years;
- our discussions with regulators regarding our first-generation seasonal influenza vaccine candidate (mRNA-1010), and our intent to file for regulatory approval in 2024;
- the potential of our platform to address rare genetic diseases, and our plans to advance propionic acidemia (PA) and methylmalonic acidemia (MMA) programs into pivotal studies in 2024;
- our ability to deliver on the next-generation pipeline and platform, including the commencement of additional clinical trials;
- our ability to successfully contract with third-party suppliers, distributors and manufacturers;
- our ability and the ability of third parties with whom we contract to successfully manufacture, supply and distribute our products, at scale, as well as drug substances, delivery vehicles and product candidates for preclinical and clinical use;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our commercial products, product candidates and technology, including our ability to enter into license agreements, and our expectations regarding pending legal proceedings related to our intellectual property;
- the timing of initiation, progress, completion, results (including interim data) and cost of our clinical trials, preclinical studies and research and development programs, as well as those of our collaborators;
- participant enrollment in our clinical trials, including enrollment demographics and timing;
- potential advantages of mRNA as compared to traditional medicine;
- our ability to obtain and maintain regulatory approval for our products;
- our ability to successfully commercialize our products, if approved, including in light of the size and growth potential of the markets for our products and the degree of market acceptance of our products;
- the pricing and reimbursement of our medicines, if approved;

- the buildout of our manufacturing and commercial operations, including our partnerships with various governments to establish mRNA vaccine manufacturing facilities;
- our financial performance and estimates of our future expenses, revenues and capital requirements;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic collaborations or other agreements with collaborators with development, regulatory and commercialization expertise;
- legal and regulatory developments in the United States and foreign countries;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- our ability to attract and retain key scientific, manufacturing, regulatory, commercial and management personnel; and
- developments relating to our competitors and our industry.

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on forward-looking statements. Factors that may cause actual results or events to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms "Moderna," the "Company," "we," "us" and "our" in this Annual Report on Form 10-K refer to Moderna, Inc. and its consolidated subsidiaries.

TRADEMARKS

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business

Moderna is a leader in the creation of the field of messenger RNA (mRNA) medicine. By working at the intersection of science, technology and health for more than a decade, we have developed medicines at unprecedented speed and efficiency, including one of the earliest and most effective COVID-19 vaccines.

Our mRNA platform has enabled the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases. With a unique culture and a global team driven by the Moderna values and mindsets to responsibly change the future of human health, we strive to deliver the greatest possible impact to people through mRNA medicines.

Our first commercial product, Spikevax (our COVID-19 vaccine), has helped hundreds of millions of people worldwide combat COVID-19. SARS-CoV-2, the virus that causes COVID-19, continues to evolve and in 2023, the COVID-19 vaccine market transitioned to an endemic, seasonal commercial market. To adapt to the evolving market, we significantly resized our manufacturing infrastructure to help position our COVID-19 franchise for future profitability. We achieved 2023 net product sales of $6.7 billion, with $6.1 billion of COVID-19 vaccine sales, and recognition of approximately $0.6 billion of deferred revenue related to our efforts with Gavi, The Vaccine Alliance. In the United States, we achieved 48% market share in the retail market for the 2023 fall season, compared to 37% in the 2022 fall season.

Beyond COVID-19, in 2023, we prepared for the potential 2024 launch of our investigational respiratory syncytial virus (RSV) vaccine for adults, which we expect to further demonstrate the commercial potential of our mRNA platform. In cancer, we reported additional data from our Phase 2b trial evaluating our individualized neoantigen therapy (INT) in combination with Merck's KEYTRUDA in melanoma patients compared to KEYTRUDA alone. The treatment continued to show significant and clinically meaningful improvement in recurrence-free survival and reduced the risk of recurrence or death by 49%. We believe that these data, with a median follow-up of approximately three years, demonstrate the durability of the therapy, and we have initiated Phase 3 studies in the adjuvant setting in patients with high-risk melanoma and non-small cell lung cancer. We and Merck plan to rapidly expand our clinical trials to additional tumor types.

Having demonstrated clinical benefit in multiple infectious disease areas and skin cancer, as well as potential clinical benefit for several rare genetic diseases, we continue to advance a broad and diverse pipeline and are focused on execution to deliver for patients. Our pipeline includes 45 therapeutic and vaccine programs, nine of which are in late-stage development.

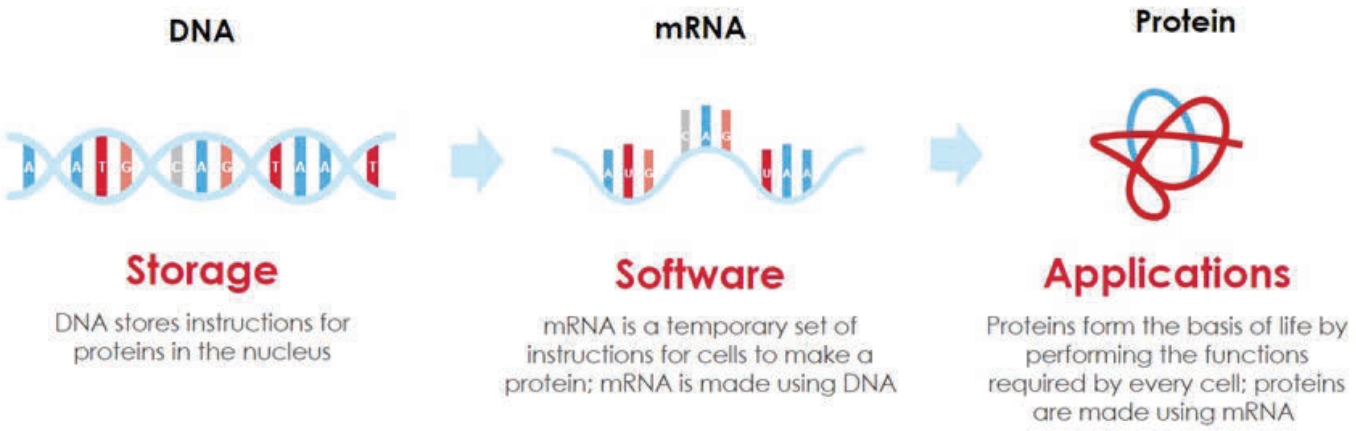
THE mRNA OPPORTUNITY

mRNA, the software of life

mRNA transfers the information stored in our genes to the cellular machinery that makes all the proteins required for life. Our genes are stored as sequences of DNA which contain the instructions to make specific proteins. DNA serves as a hard drive, safely storing these instructions in the cell's nucleus until they are needed by the cell.

When a cell needs to produce a protein, the instructions to make that protein are copied from the DNA to mRNA, which serves as the template for protein production. Each mRNA molecule contains the instructions to produce a specific protein with a distinct function in the body. mRNA transmits those instructions to cellular machinery, called ribosomes, that make copies of the required protein.

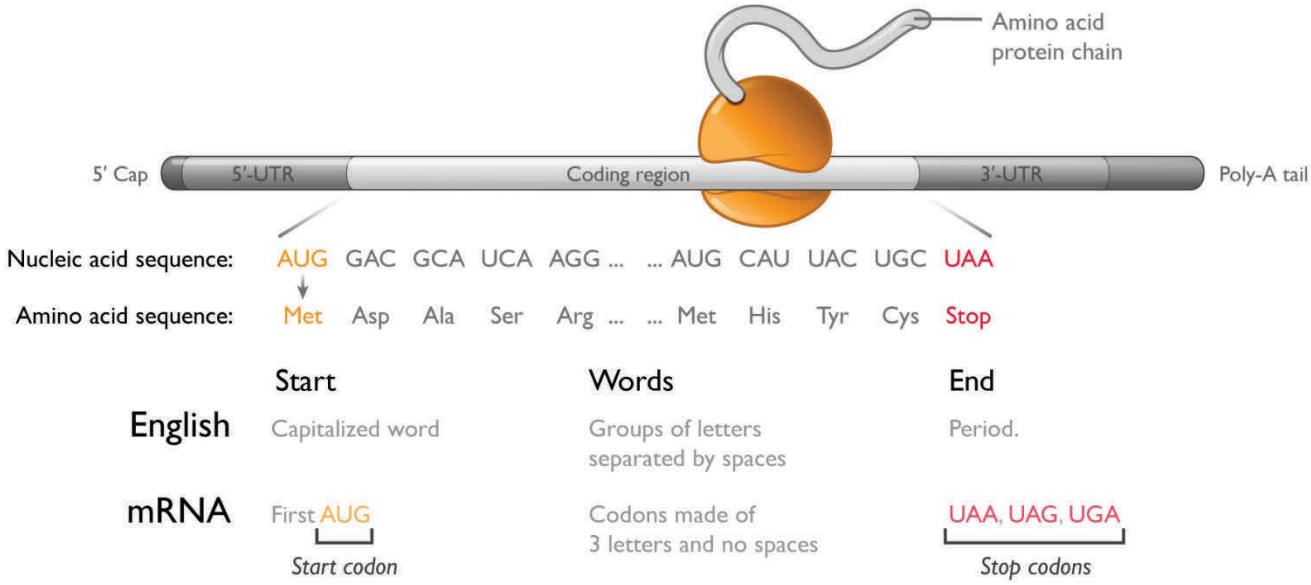
We see mRNA functioning as the "software of life." Every cell uses mRNA to provide real time instructions to make the proteins necessary to drive all aspects of biology, including in human health and disease. This was codified as the central dogma of molecular biology over 60 years ago, and is exemplified in the schematic below.



The structure of mRNA

mRNA is a linear polymer comprising four monomers called nucleotides: adenosine (A), guanosine (G), cytosine (C) and uridine (U). Within the region of the molecule that codes for a protein (the coding region), the sequence of these four nucleotides forms a language made up of three-letter words called codons. The first codon, or start codon (AUG), signals where the ribosome should start protein synthesis. To know what protein to make, the ribosome then progresses along the mRNA one codon at a time, appending the appropriate amino acid to the growing protein. To end protein synthesis, three different codons (UAA, UAG, and UGA) serve as stop signals, telling the ribosome where to terminate protein synthesis. In total, there are 64 potential codons, but only 20 amino acids that are used to build proteins; therefore, multiple codons can encode for the same amino acid.

The process of protein production is called translation because the ribosome is reading in one language (a sequence of codons) and outputting in another language (a sequence of amino acids). The coding region is analogous to a sentence in English. Much like a start codon, a capitalized word can indicate the start of a sentence. Codons within the coding region resemble groups of letters representing words. The end of the sentence is signaled by a period in English, or a stop codon for mRNA.



In every cell, hundreds of thousands of mRNAs make hundreds of millions of proteins every day. A typical protein contains 200-600 amino acids; therefore, a typical mRNA coding region ranges from 600-1,800 nucleotides. In addition to the coding region, mRNAs contain four other key features: (1) the 5' untranslated region (5'-UTR); (2) the 3' untranslated region (3'-UTR); (3) the 5' cap; and (4) a 3' polyadenosine (poly-A) tail. The sequence of nucleotides in the 5'-UTR influences how efficiently the ribosome initiates protein synthesis, whereas the sequence of nucleotides in the 3'-UTR contains information about which cell types should translate that mRNA and how long the mRNA should last. The 5' cap and 3' poly-A tail enhance ribosome engagement and protect the mRNA from attack by intracellular enzymes that digest mRNA from its ends.

The intrinsic advantages of using mRNA as a medicine

mRNA possesses inherent characteristics that we believe position it to have a profound impact on human health:

- **mRNA is used by every cell to produce all proteins:** mRNA is used to make every type of protein, including secreted, membrane and intracellular proteins, in varying quantities over time, in different locations and in various combinations. Given the universal role of mRNA in protein production, we believe that mRNA medicines could have broad applicability across human disease.
- **Making proteins inside one's own cells mimics human biology:** Tailored mRNA can be sent into cells to instruct them to produce specific protein therapeutics or vaccine antigens and provides certain advantages over traditional approaches to medicine, where a protein or chemical is introduced to the body.
- **mRNA has a simple and flexible chemical structure:** Each mRNA molecule comprises four chemically similar nucleotides to encode proteins made from up to 20 chemically different amino acids. To make the full diversity of possible proteins, only simple sequence changes are required in mRNA, instead of starting from scratch for each new vaccine or therapy.
- **mRNA has classic pharmacologic features:** mRNA possesses many of the attractive pharmacologic features of most modern medicines, including reproducible activity, predictable potency and well-behaved dose dependency; mRNA also provides the ability to adjust dosing based on an individual patient's needs, including stopping or lowering the dose, to seek to promote safety and tolerability.

Our ability to rapidly develop, manufacture and commercialize vaccines against COVID-19 demonstrates the potential mRNA medicines have to help people and patients in far-reaching ways that could exceed the impact of traditional approaches to medicine.

We believe that the main advantages of mRNA as compared to traditional medicine are:

1. **mRNA could create an unprecedented abundance and diversity of medicines.** mRNA's breadth of applicability has the potential to create an extraordinary number of new mRNA medicines that are currently beyond the reach of recombinant protein technology.

2. **Advances in the development of our mRNA medicines reduce risks across our portfolio.** mRNA medicines share fundamental features that can be leveraged across our portfolio. We believe that once safety and proof of protein production has been established in one program, the technology and biology risks of related programs that use similar mRNA technologies, delivery technologies and manufacturing processes will decrease significantly.

3. **mRNA technology can accelerate discovery and development.** The software-like features of mRNA enable rapid *in silico* design and the use of automated high-throughput synthesis processes that permit discovery to proceed in parallel rather than sequentially. We believe these mRNA features can also accelerate drug development by allowing the use of shared manufacturing processes and infrastructure.

4. **The ability to leverage shared processes and infrastructure can drive significant capital efficiency over time.** We believe the manufacturing requirements of different mRNA medicines are similar and that at commercial scale, a portfolio of mRNA medicines will benefit from shared capital expenditures.

OUR STRATEGY

We believe that the development of mRNA medicines represents a significant breakthrough for patients, our industry and human health globally. Our success in developing one of the earliest and most effective COVID-19 vaccines, at unprecedented speed and efficiency, demonstrates the promise of mRNA medicine. Our COVID-19 vaccine has helped hundreds of millions of people worldwide combat COVID-19. Beyond COVID-19, our platform continues to be highly productive, with 45 programs currently in development, spanning infectious diseases, immuno-oncology, rare diseases and autoimmune diseases.

Across our respiratory vaccines, latent and other vaccines, oncology and rare disease franchises, we are aiming to launch up to 15 new products over the next five years. We have formulated strategic objectives to help enable our near- and long-term goals:

1. **Deliver an unrivalled respiratory vaccine franchise.** We are developing vaccines against COVID-19, seasonal flu and RSV individually, while pursuing parallel development of combination vaccines. Recognizing that COVID-19 is likely to pose an ongoing health burden, we are making it an important piece of our business with our vaccines against COVID-19 and our investigational combination vaccine against flu and COVID-19. In parallel, we are preparing for the potential 2024 launch of our investigational RSV vaccine for older adults, which is expected to further demonstrate the commercial potential of our mRNA platform. We expect that our anticipated respiratory product launches in 2024 and 2025 will allow us to recognize efficiencies from our growing pipeline.

2. **Advance multiple latent virus and other vaccines.** We are developing vaccines against latent and other viruses with unmet or underserved needs, including cytomegalovirus (CMV), Epstein-Barr virus (EBV), herpes simplex virus (HSV), varicella zoster virus (VZV), norovirus, HIV and Lyme disease. We anticipate potential efficacy data from the pivotal Phase 3 study of our CMV vaccine candidate in 2024. CMV is the most common infectious cause of birth defects in the United States and has been designated as a top priority in new vaccine development by the U.S. National Academy of Medicine for more than two decades.

3. **Accelerate a large portfolio of late-stage clinical trials in INT to deliver a transformative impact in cancer treatments.** In 2023, we reported data from our Phase 2b trial evaluating our INT in combination with Merck's KEYTRUDA in melanoma patients compared to KEYTRUDA alone, which we believe demonstrates the durability of the therapy. We have launched Phase 3 trials for both adjuvant melanoma and non-small cell lung cancer (NSCLC), and plan to expand the development program to additional tumor types.

4. **Accelerate investment in three rare disease programs to pursue potential launches.** We have demonstrated the potential for clinical benefit in three different rare genetic diseases (propionic acidemia (PA), methylmalonic acidemia (MMA) and glycogen storage disease type 1a (GSD1a)), and expect to advance our PA and MMA programs into pivotal studies in 2024.

5. **Deliver the next-generation pipeline and platform.** We have demonstrated clinical benefit in multiple infectious disease vaccines and in skin cancer, as well as potential clinical benefit in three different rare genetic diseases. Based on these clinical successes, we continue to advance a broad and diverse pipeline and are focused on execution to deliver for patients. We plan to continue to invest in our science and our platform to expand mRNA applications and advance new programs into clinical studies.

OUR PLATFORM

Overview of our platform

Our mRNA "platform" refers to our accumulated knowledge and capabilities in basic and applied sciences. Our platform incorporates advances across three key components—mRNA, delivery and the manufacturing process— to advance our medicines. We integrate these components and combine different versions of mRNA delivery and process into each of our medicines.

Our platform: mRNA science advancements

We continue to invest in both basic and applied research, seeking to advance both the state of our technology and the state of the scientific community's understanding of mRNA. Examples of advances in mRNA science that combine nucleotide chemistry, sequence engineering and targeting elements are described below.

mRNA chemistry: Modified nucleotides to mitigate immune system activation: The innate immune system has evolved to protect cells from foreign RNA, such as viral RNA, by inducing inflammation and suppressing mRNA translation once detected. Many cells surveil their environment through sensors called toll-like-receptors (TLRs). These include types that are activated by the presence of double-stranded RNA (TLR3) or uridine containing RNA fragments (TLR7, TLR8). Additionally, all cells have cytosolic double-stranded RNA, sensors, including retinoic acid inducible gene-I (RIG-I) that are sensitive to foreign RNA inside the cell.

The immune and cellular response to mRNA is complex, context specific, and often linked to the sensing of uridine. To minimize undesired immune responses to our potential mRNA medicines, our platform employs chemically-modified uridine nucleotides to minimize recognition by both immune cell sensors such as TLR3/7/8, and broadly-distributed cytosolic receptors such as RIG-I.

mRNA sequence engineering: Maximizing protein expression: mRNA exists transiently in the cytoplasm, during which time it can be translated into thousands of proteins before eventually being degraded. Our platform applies bioinformatic, biochemical, and biological screening capabilities, most of which have been invented internally that aim to optimize the amount of protein produced per mRNA. We have identified proprietary sequences for the 5'-UTR that have been observed to increase the likelihood that a ribosome bound to the 5'-end of the mRNA transcript will find the desired start codon and reliably initiate translation of the coding region. We additionally design the nucleotide sequence of the coding region to maximize its successful translation into protein.

Targeting elements: Enabling tissue-targeted translation: All nucleated cells in the body are capable of translating mRNA, resulting in pharmacologic activity in any cell in which mRNA is delivered and translated. To minimize or prevent potential off-target effects, our platform employs technologies that regulate mRNA translation in select cell types. Cells often contain short RNA sequences, called microRNAs or miRNAs, that bind to mRNA to regulate protein translation at the mRNA level. Different cell types have different concentrations of specific microRNAs, in effect giving cells a microRNA signature. microRNA binding directly to mRNA effectively silences or reduces mRNA translation and promotes mRNA degradation. We design microRNA binding sites into

the 3'-UTR of our potential mRNA medicines so that if our mRNA is delivered to cells with such microRNAs, it will be minimally translated and rapidly degraded.

Our platform: Delivery science

Our mRNA can, in specific instances, be delivered by direct injection to a tissue in a simple saline formulation without lipid nanoparticles (LNPs) to locally produce small amounts of pharmacologically active protein. However, the blood and interstitial fluids in humans contain significant RNA degrading enzymes that rapidly degrade any extracellular mRNA and prevent broader distribution without LNPs. Additionally, cell membranes tend to act as a significant barrier to entry of large, negatively-charged molecules such as mRNA. We have therefore invested heavily in delivery science and have developed LNP technologies to enable delivery of larger quantities of mRNA to target tissues.

LNPs are generally composed of four components: an amino lipid, a phospholipid, cholesterol, and a pegylated-lipid (PEG-lipid). Each component, as well as the overall composition, or mix of components, contributes to the properties of each LNP system. LNPs containing mRNA injected into the body rapidly bind proteins that can drive uptake of LNPs into cells. Once internalized in endosomes within cells, the LNPs are designed to escape the endosome and release their mRNA cargo into the cell cytoplasm, where the mRNA can be translated to make a protein and have the desired therapeutic effect. Any mRNA and LNP components that do not escape the endosome are typically delivered to lysosomes where they are degraded by the natural process of cellular digestion. Examples of tools we developed by using our platform include proprietary LNP formulations that address the steps of mRNA delivery, including cell uptake, endosomal escape, and subsequent lipid metabolism, and for avoidance of counterproductive interactions with the immune system.

Chemistry: Novel lipid chemistry to potentially improve safety and tolerability: Our proprietary LNP systems are designed to be highly tolerated and minimize any LNP vehicle-related toxicities with repeat administration *in vivo*. To overcome limitations of previous LNP formulations, we have engineered amino lipids to avoid the immune system and to be rapidly biodegradable relative to prior lipids.

Composition: Proprietary LNPs enhance delivery efficiency: Our platform includes extensive in-house expertise in medicinal chemistry, which we have applied to design large libraries of novel lipids. Using these libraries in combination with our discovery biology capabilities, we have conducted high throughput screens for desired LNP properties and believe that we have made fundamental discoveries in preclinical studies about the relationships between structural motifs of lipids and LNP performance for protein expression.

Surface properties: Novel LNP design to avoid immune recognition: We have designed our proprietary LNP systems for sustained pharmacology upon repeat dosing by eliminating or altering features that activate the immune system. These are based on insights into the surface properties of LNPs. Upon repeated dosing, surface features on traditional LNPs such as amino lipids, phospholipids, and PEG-lipids, can be recognized by the immune system, leading to rapid clearance from the bloodstream, a decrease in potency upon repeat dosing, and an increase in inflammation. Based on our insights into these mechanisms, we have engineered our LNP systems to reduce or eliminate undesirable surface features. In clinical studies for our systemic therapeutic product candidates that use our novel LNP systems, we have been able to repeat dose with negligible or undetectable loss in potency, liver damage, and immune system activation.

Our platform: Manufacturing process science

We invest significantly in manufacturing process science to impart more potent features to our mRNA and LNPs, and to invent the technological capabilities necessary to manufacture our mRNA medicines at scales ranging from micrograms to kilograms, as well as achieve pharmaceutical properties such as solubility and shelf life. We view developing these goals of manufacturing and pharmaceutical properties as appropriate for each program, based on its stage of development.

mRNA manufacturing process: Improving pharmacology: Our platform creates mRNA using a cell-free approach called *in vitro* transcription in which an RNA polymerase enzyme binds to and transcribes a DNA template, adding the nucleotides encoded by the DNA to the growing RNA strand. Following transcription, we employ proprietary purification techniques to ensure that our mRNA is free from undesired synthesis components and impurities that could activate the immune system in an indiscriminate manner. Applying our understanding of the basic science underlying each step in the manufacturing process, we have designed proprietary manufacturing processes to impart desirable pharmacologic features, for example increasing potency in a vaccine.

LNP manufacturing process: Improving pharmacology: Our platform technology includes synthetic processes to produce LNPs. Traditionally LNPs are assembled by dissolving the four molecular components, amino lipid, phospholipid, cholesterol, and PEG-lipid, in ethanol and then mixing this with mRNA in an aqueous buffer. The resulting mixture is then purified to isolate LNPs from impurities. Such impurities include molecular components that have not been incorporated into particles, un-encapsulated mRNA that could activate the immune system, and particles outside of the desired size range. Going beyond optimization of traditional manufacturing processes, we have invested in understanding and measuring the various biochemical and physical interactions during LNP assembly and purification. We have additionally developed state-of-the-art analytical techniques necessary to characterize our LNPs and biological systems to analyze their *in vitro* and *in vivo* performance. With these insights, we have identified manufacturing process parameters that drive LNP performance, for example, the potency in a secreted therapeutic setting. These insights have allowed us to make significant improvements in the efficiency of our processing and the potency of our LNPs.

OUR MODALITIES

Our vision for harnessing the power of mRNA through modalities

Within our platform, we invest in science to invent novel ways to deliver mRNA into various cell types. Each novel delivery system is a new application, which we call a "modality." While the programs within a modality may target diverse diseases, they share similar mRNA characteristics and manufacturing processes to achieve shared product features.

We believe that the high technological correlation within a modality allows us to rapidly accelerate the expansion of programs within that modality based on learnings from the earlier programs, while the lower technology correlation between modalities allows us to compartmentalize the technology risks. Additionally, because programs within a modality pursue diverse diseases, they often have uncorrelated biology risk. Each time we add a modality and a new product candidate to our portfolio, we create a network effect because each incremental program can help us gain additional insight into the other programs in our pipeline.

Although developing a new modality is difficult, time-consuming and expensive, we believe our experience and technology provide us with unique advantages in the development of mRNA medicines. Over the last decade, we have developed a number of modalities, each with one or many product candidates in the clinic. We believe that our ongoing investments in our platform will lead to the identification of additional modalities and expand the utility of our existing modalities and the diversity of our pipeline.

Our current modalities

Our current modalities are described below. More detail regarding our current programs in each modality is provided below under "— Our Pipeline."

- **Infectious disease vaccines:** The goal of our infectious disease vaccines is to safely pre-expose the immune system to a small quantity of a protein from a pathogen, called an antigen, so that the immune system is prepared to fight the pathogen if exposed in the future, and prevent infection or disease. Our infectious disease vaccines include those targeting respiratory viruses, latent viruses and enteric viruses, as well as bacterial vaccines and public health vaccines. We believe mRNA vaccines have several advantages, including the ability to mimic many aspects of various infections, the ability to combine antigens for compelling product profiles, the rapid discovery and advancement of programs into the clinic and the capital efficiency and speed from shared manufacturing processes and infrastructure.

- **Cancer vaccines and therapeutics:** The goal of a cancer therapy is to safely expose the patient's immune system to tumor-related antigens, known as neoantigens, to enable the immune system to elicit a more effective antitumor response. Our cancer therapies modality is focused on the use of mRNA to express neoantigens found in a particular tumor in order to elicit an immune response via T cells that recognize those neoantigens, and therefore the tumor. These neoantigens can either be unique to a patient or can be related to a driver oncogene found across subsets of patients. Recent breakthroughs in cancer immunotherapy, such as checkpoint inhibitors and chimeric antigen receptor T cell therapies, have demonstrated that powerful antitumor responses can be achieved by activating antigen specific T cells. We believe one approach to improve the efficacy of checkpoint inhibitors is to develop vaccines that increase both the number and antitumor activity of a patient's T cells that recognize tumor neoantigens. We believe that mRNA technology is an attractive approach for cancer therapies for several reasons, including the ability to deliver multiple personalized neoantigens in a single mRNA molecule, and that mRNA encoding for neoantigens is translated and processed by patients' endogenous cellular mechanisms for presentation to the immune system.

- **Rare disease intracellular therapeutics:** The goal of this modality is to provide intracellular proteins, such as intracellular enzymes and organelle-specific proteins, as safe, tolerable, and efficacious therapies. Our mRNA medicines aim to increase levels of intracellular proteins to achieve a therapeutic effect in one or more tissues or cell types and our initial focus is on rare genetic diseases. Intracellular therapeutics are not currently addressable with recombinant proteins, which are typically

administered systematically and cannot reach inside of the cell. Our potential advantages in these areas include encoding for intracellular and organelle-specific proteins and the production of hard-to-make or complex proteins with native post-translational modifications.

- **Intratumoral immuno-oncology:** The goal of this modality is to treat or cure cancer by transforming the tumor microenvironment to drive anti-cancer T cell responses against tumors. The outlook for any patients with advanced cancer remains poor, especially in patients with tumors that have little immune system engagement, sometimes termed immunologically "cold." In conjunction with a checkpoint inhibitor, we aim to activate the immune system against these otherwise immunologically cold tumors. Intratumoral administration allows for localized effect of these therapeutics that could be toxic if administered systemically. We believe our approach to intratumoral immuno-oncology using mRNA medicines could complement checkpoint inhibitors and has several advantages over recombinant protein-based drugs, including production of membrane-associated immune stimulatory proteins, multiplexing of mRNA to access multiple immune stimulatory pathways and creation of engineered mRNA sequences to reduce off-target effects.

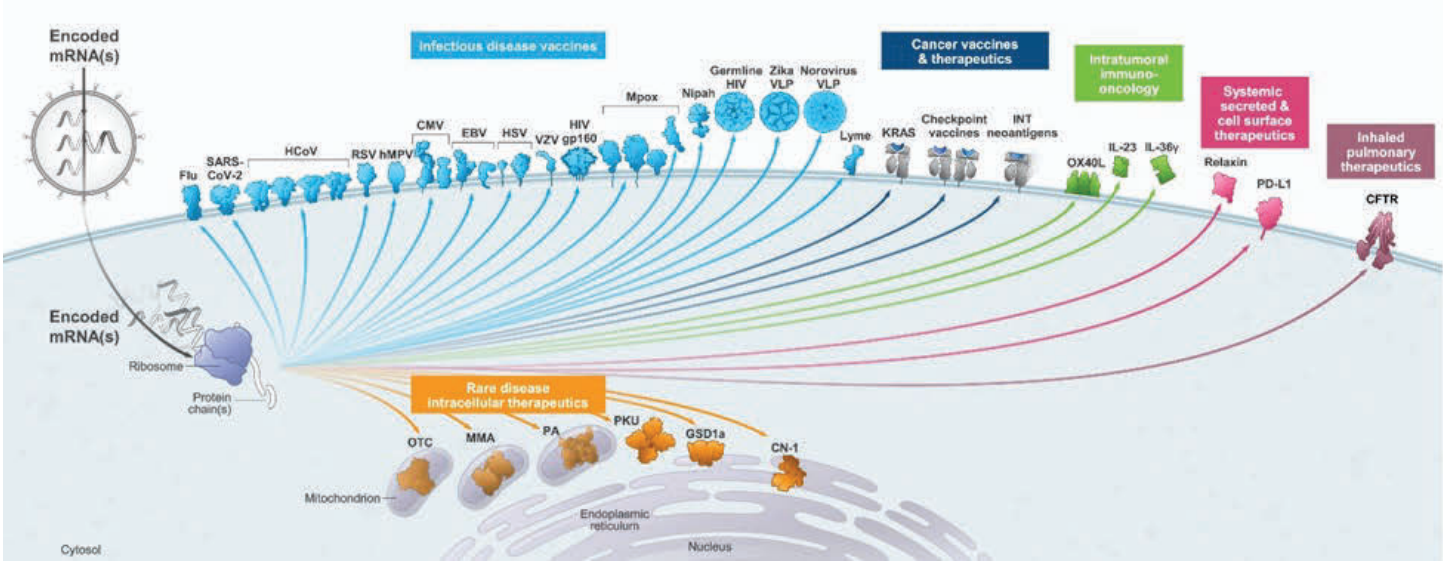
- **Inhaled pulmonary therapeutics:** The goal of this modality is to develop mRNA medicines that can be delivered to the lung as safe, tolerable and efficacious therapies. We are developing nebulized LNP formulations that can transfect airway epithelial cells to deliver mRNA into the lungs of patients in order to express proteins coded in the mRNA. We aim to leverage our technology for pulmonary diseases in patients for whom there are no existing effective therapies. Our potential advantages in these areas include lung-associated production of secreted, membrane-associated or intracellular hard-to-make or complex proteins.

- **Systemic secreted and cell surface therapeutics:** The goal of this modality is to provide secreted proteins, such as antibodies or enzyme replacement therapies across a wide range of diseases, such as heart failure, infectious diseases, and rare genetic diseases. Our mRNA medicines instruct various cells of the human body to secrete proteins for therapeutic effect. Systemically delivered, secreted and cell surface therapeutics, we believe, would allow us to target areas of biology that cannot be addressed using recombinant proteins. Our potential advantages in this area include encoding for hard-to-make or complex secreted or membrane-associated proteins, multiplexing of mRNA to encode for multiple proteins with complementary activity, native post-translational modifications and sustained production of proteins, which can increase exposure to proteins with short half-lives.

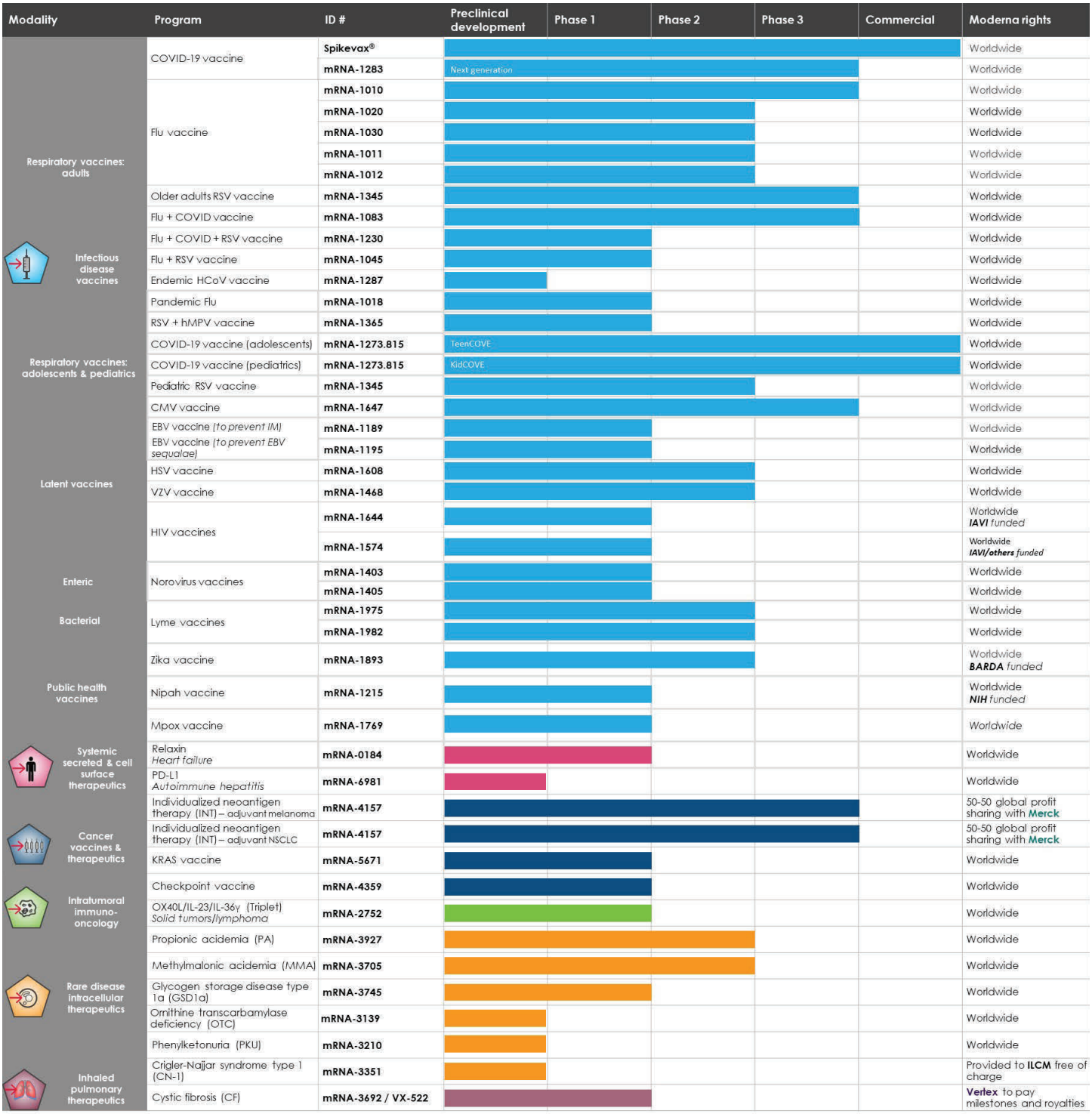
OUR PIPELINE

Over the last decade, we have advanced in parallel a diverse development pipeline that currently consists of 45 therapeutic and vaccine programs, nine of which are in late-stage development. The scope of our pipeline reflects the breadth of biology addressable using mRNA technology. Our selection process for advancing new product candidates reflects both program-specific and portfolio-wide considerations. Program-specific criteria include, among other relevant factors, the severity of the unmet medical need, the biology risk of our chosen target or disease, the feasibility of clinical development, the costs of development and the commercial opportunity. Portfolio-wide considerations include the ability to demonstrate technical success for our platform components within a modality, thereby increasing the probability of success and learnings for subsequent programs in the modality and in some cases in other modalities.

The diversity of proteins made from mRNA within our development pipeline is shown in the figure below.



Our full pipeline, grouped by modalities, is shown in the figure below:



INFECTIOUS DISEASE VACCINES MODALITY

We have 31 different infectious disease vaccine programs, of which 30 have entered the clinic. Our infectious disease vaccines modality includes vaccines against respiratory viruses, latent viruses and enteric viruses, as well as bacterial vaccines and public health vaccines.

Infectious disease vaccines: Vaccines against respiratory viruses

COVID-19 vaccines (mRNA-1273/Spikevax®, next-generation mRNA-1283)

Our COVID-19 vaccine is approved or authorized for use in more than 70 countries. COVID-19 is caused by the SARS-CoV-2 virus that was first identified in humans in 2019, driving a global pandemic resulting in millions of deaths. The risk of mortality increases with age and the risk of severe disease and mortality increases for persons with certain pre-existing diseases or comorbid conditions, such as cardiovascular disease, diabetes, chronic lung disease and obesity.

Our COVID-19 vaccine continues to be a key tool in fighting COVID-19 as the SARS-CoV-2 virus evolves. As part of our strategy to combat the virus, we have continued to develop and assess variant-specific versions of our COVID-19 vaccine. In September 2023, we received regulatory approvals in major markets for our updated COVID-19 vaccine (mRNA-1273.815), which targets the XBB.1.5 subvariant of SARS-CoV-2. We developed mRNA-1273.815 in accordance with regulatory guidance, with the goal of broadening vaccine-induced immunity and providing protection against circulating SARS-CoV-2 XBB lineage variants. We have also observed preliminary clinical trial data showing that mRNA-1273.815 generates a robust immune response against other variants of SARS-CoV-2.

The FDA has approved mRNA-1273.815 for individuals ages 12 years and older, and granted Emergency Use Authorization for individuals six months through 11 years of age. mRNA-1273.815 has also been authorized for individuals six months and older in other key markets, including the EU, Canada and Japan.

Forward-looking references to our COVID-19 vaccine in this Annual Report on Form 10-K may include future modifications to mRNA-1273 or other product candidates that are designed to provide protection against variants of the SARS-CoV-2 virus.

In addition to our approved or authorized COVID-19 vaccines, we have advanced other COVID-19 vaccine candidates into the clinic as part of our effort to fight the evolving SARS-CoV-2 virus. Our next-generation COVID-19 vaccine, which is designed to be refrigerator-stable (mRNA-1283), is in a pivotal Phase 3 study, and we anticipate data from the trial in the first half of 2024. Our goal with mRNA-1283 is to facilitate easier distribution and administration by healthcare providers. Further, as SARS-CoV-2 evolves, we continue to perform continuous epidemiological monitoring, genomic surveillance and risk assessments of variants of concern to determine which new variants may have the ability to circumvent immunity provided by currently approved COVID-19 vaccines. For variants that appear to be growing in circulation and have evolved the ability to evade immunity, we proactively develop new product candidates. We have taken several of these candidates to clinical trials, and our monitoring activities allow for expedited delivery of new vaccines in the event that regulatory agencies request specific vaccine composition updates to address public health needs.

COVID-19 Commercial, Manufacturing and Supply Updates

Net product sales of our COVID-19 vaccine were $6.7 billion in 2023, which accounted for all of our product revenues. We anticipate that sales of our COVID-19 vaccine in 2024 will provide a significant portion of our commercial revenues for the coming year. Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and international organizations. In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and international organizations.

With COVID-19 entering an endemic phase in 2023, we saw increased seasonality for sales, with greater demand in the fall/winter season in each hemisphere as countries sought to provide vaccinations to their populations. We expect this seasonality to continue in future years in the endemic market. As such, we resized our global manufacturing footprint in 2023 to account for demand in the endemic market. For further information on the sales and manufacturing of our COVID-19 vaccine, see "–Manufacturing" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

RSV vaccine (mRNA-1345)

Respiratory syncytial virus (RSV) is one of the most common causes of lower respiratory disease in children under the age of five and in older adults. Populations that are especially vulnerable to developing severe RSV infections include infants, young children, children and adults with chronic medical conditions and older adults. Most children are infected at least once by age two. In the United States, it is estimated that over two million children younger than five receive medical attention and up to 80,000 are hospitalized due to RSV infection annually. RSV also causes a substantial burden of respiratory illness in older adults. RSV infection causes up to 160,000 hospitalizations and up to 10,000 deaths per year in adults aged 65 years or older in the United States.

We are developing an RSV vaccine (mRNA-1345) for children, pregnant women and adults. mRNA-1345 encodes an engineered form of the RSV F protein stabilized in the prefusion conformation and is formulated in our proprietary LNP. In January 2023, we announced that mRNA-1345 had met primary efficacy endpoints in the pivotal Phase 3 trial in older adults, ages 60 and older. mRNA-1345 demonstrated vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; $p<0.0001$) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; $p=0.0078$). mRNA-1345 was generally well-tolerated with no safety concerns identified. Based on the positive topline data from the pivotal Phase 3 efficacy trial, the FDA granted mRNA-1345 Breakthrough Therapy Designation for the prevention of RSV-LRTD in adults 60 years or older.

We have submitted marketing authorization applications in several major markets for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults 60 years or older. We expect regulatory approvals beginning in the first half of 2024.

We have additional Phase 3 studies ongoing in adults to explore co-administration with licensed flu or COVID-19 vaccines, revaccination with mRNA-1345 and expansion to adults aged 18 and older who are at high risk for severe RSV disease. In pediatrics, mRNA-1345 is ongoing in Phase 1 and Phase 2 studies, and we are conducting a Phase 2 study in maternal populations.

Seasonal influenza vaccines (mRNA-1010, mRNA-1011, mRNA-1012, mRNA-1020 and mRNA-1030)

The World Health Organization (WHO) estimates that seasonal influenza viruses cause three to five million cases of severe illness and 290,000 to 650,000 deaths each year, resulting in a severe challenge to public health. Currently licensed seasonal influenza vaccines rarely exceed 60% overall effectiveness and can provide low effectiveness during years when the circulating viruses do not match the strains selected for the vaccine antigens.

Our mRNA seasonal influenza vaccine program is taking an iterative approach to development. Our first-generation seasonal influenza vaccine candidate (mRNA-1010) encodes for the hemagglutinin (HA) proteins of the strains recommended by the WHO. We are intending to subsequently improve upon the first-generation candidate through inclusion of additional HA antigens that could provide expanded coverage of co-circulating strains, as well as broadening protection through the addition of another influenza protein, the neuraminidase (NA). We also aim to work with the WHO, regulators and public health authorities to enable strain selection closer to the influenza season to provide a better match to the circulating viruses.

The inclusion of additional HA antigens is being tested in our mRNA-1011/1012 programs, and the addition of NA antigens is being tested in our mRNA-1020/1030 programs. We aim to ultimately combine both approaches into a single next-generation vaccine.

In February 2023, we announced interim results from the P301 study of mRNA-1010. The results indicated that mRNA-1010 achieved higher seroconversion rates for A/H3N2 and A/H1N1, as well as superiority on geometric mean titer ratios for A/H3N2 and non-inferiority on geometric mean titer rations for A/H1N1. Non-inferiority was not met for either endpoints for the influenza B/Victoria- or B/Yamagata-lineage strains. mRNA-1010 showed an acceptable safety and tolerability profile. In April 2023, we announced the P302 study of mRNA-1010 did not accrue sufficient cases at the interim efficacy analysis to declare early success in the Phase 3 Northern Hemisphere efficacy trial. In September 2023, we announced the P303 immunogenicity and safety study of mRNA-1010 met all 8 co-primary endpoints with an updated formulation that was able to generate an improved immune response to influenza B strains. mRNA-1010 also elicited higher titers than the licensed comparator against all strains in this study. An additional study to compare immunogenicity of mRNA-1010 against an enhanced influenza vaccine comparator is currently ongoing. Conversations with regulators regarding filing for approval of mRNA-1010 are currently ongoing and we intend to file for regulatory approval in 2024.

Phase 1/2 studies for our mRNA-1011/1012 and mRNA-1020/1030 programs have been initiated and interim results have been presented at scientific meetings.

Combination vaccines (mRNA-1083, mRNA-1230, mRNA-1045 and mRNA-1365)

We are developing combination vaccine candidates to protect against a range of respiratory diseases.

mRNA-1083, our next-generation COVID-19 and seasonal influenza combination vaccine, encodes the same antigens as our first-generation seasonal influenza vaccine (mRNA-1010) and our next-generation COVID-19 vaccine (mRNA-1283). In a Phase 1/2 trial, mRNA-1083 showed strong immunogenicity against influenza and COVID-19 compared to licensed standalone vaccines, with an acceptable reactogenicity and safety profile. In October 2023, we initiated a Phase 3 trial in adults 50 years and older. The trial is fully enrolled and data is anticipated in 2024.

We are also conducting Phase 1 studies for mRNA-1230, our COVID-19, seasonal flu and RSV combination vaccine, and mRNA-1045, our seasonal flu and RSV combination vaccine.

Enrollment is ongoing in a Phase 1 trial of mRNA-1365, our RSV and hMPV combination vaccine, in children five to under 24 months of age. In February 2024, the FDA granted Fast Track Designation for mRNA-1365.

Infectious disease vaccines: Vaccines against latent viruses

CMV vaccine (mRNA-1647)

Human cytomegalovirus (CMV) is a common human pathogen and member of the herpes virus family. Congenital CMV results from infected mothers transmitting the virus to their unborn child and it is the leading infectious cause of birth defects in the United States, with approximately 25,000 newborns in the U.S. infected annually. There is currently no available vaccine for CMV and a vaccine that leads to durable immunity in women of child-bearing age would address a critical unmet need in the prevention of congenital CMV infection.

Our CMV vaccine candidate, mRNA-1647, combines six mRNAs in one vaccine, which encode for two proteins located on the surface of CMV: five mRNAs encode the subunits that form the membrane-bound pentamer complex and one mRNA encodes the full-length membrane-bound glycoprotein B (gB). Both pentamer and gB are essential for CMV to infect barrier epithelial surfaces and gain access to the body, which is the first step in CMV infection. mRNA-1647 is designed to produce an immune response against both pentamer and gB for the prevention of CMV infection, which could reduce the risk of birth defects and post-transplant infections.

We are conducting an ongoing Phase 3 study for mRNA-1647, known as CMVictory, to evaluate the safety and efficacy of mRNA-1647 against primary CMV infection in female participants 16 to 40 years of age. The study is fully enrolled, both for the adult and adolescent (ages 16 to <18) cohorts. Timing of the readout will depend upon the number of CMV cases accrued in the study. We anticipate potential efficacy data from the study in 2024.

We are also conducting a Phase 1/2a study of mRNA-1647 in participants 9 to 15 years of age. We enrolled the first participant in November 2022, and the study is evaluating the safety and immunogenicity of mRNA-1647 to inform the selection of a dose level for subsequent development in this age group.

Additionally, in April 2023 we announced that a Phase 2 proof-of-concept study for mRNA-1647 in allogeneic hematopoietic cell transplant (HCT) patients had started enrollment.

EBV vaccine (mRNA-1189 and mRNA-1195)

Epstein-Barr virus (EBV) is a member of the herpesvirus family that is related to CMV and infects approximately 90% of people in the U.S. by adulthood, with primary infection typically occurring during childhood or late adolescence (approximately 50% and 89% seropositivity, respectively). EBV is the major cause of infectious mononucleosis, accounting for over 90% of the approximately one to two million cases in the U.S. each year. Infectious mononucleosis can debilitate patients for weeks to months and, in some cases, can lead to hospitalization due to complications such as splenic rupture. EBV infection is also associated with the development and progression of certain lymphoproliferative disorders, cancers and autoimmune diseases. In particular, EBV infection and infectious mononucleosis are associated with increased risk of developing multiple sclerosis, an autoimmune disease of the central nervous system.

We are developing two EBV vaccine candidates—a vaccine to prevent infectious mononucleosis (mRNA-1189) and a vaccine to prevent the longer-term sequelae of EBV infection (mRNA-1195). Similar to our CMV vaccine (mRNA-1647) product concept, we believe that an effective EBV vaccine must generate an immune response to antigens that are required for viral entry in susceptible cell types. mRNA-1189 is designed to elicit an immune response to EBV envelope glycoproteins, which are required for infection of both epithelial and B cells. mRNA-1189 contains four mRNAs encoding for these proteins encapsulated in our proprietary LNPs. mRNA-1195 encodes for entry glycoproteins and latent antigens and will be investigated in the context of post-transplant lymphoproliferative disorders and multiple sclerosis.

We are conducting Phase 1, randomized, observer-blind, placebo-controlled studies of mRNA-1189 and mRNA-1195. The primary purpose of these studies is to assess the safety, tolerability and immunogenicity of these vaccine candidates.

HSV vaccine (mRNA-1608)

Herpes simplex viruses (HSV), commonly known as herpes, are categorized into two types: HSV-1 primarily spreads by oral contact and is most commonly associated with cold sores, and HSV-2 spreads through sexual contact and is the major cause of recurrent genital herpes. Both viruses establish life-long latent infections within nearby sensory neurons from which they can reactivate and re-infect the skin. There is a significant burden of disease from HSV genital infections. Diagnosed, symptomatic genital herpes causes a reduction in quality of life, which antivirals (current standard of care) only partially restore. In the United States, approximately 18.6 million adults ages 18 to 49 years are living with HSV-2. Globally, an estimated 492 million persons have HSV-2 infection, representing 13% of the world's population aged 15 to 49 years. We believe that an HSV vaccine could deliver similar efficacy as suppressive antiviral treatments and could improve compliance and quality of life. We aim to induce a strong antibody response with neutralizing and effector functionality combined with cell-mediated immunity.

We are conducting a Phase 1/2, randomized, observer-blind, controlled, dose-ranging study of mRNA-1608, our HSV vaccine candidate against recurrent HSV-2 disease, in health adults 18 to 55 years of age with recurrent HSV-2 genital herpes. The primary purpose of this study is to assess safety and immunogenicity data, and establish a proof-of-concept of clinical benefit.

VZV vaccine (mRNA-1468)

Herpes zoster, also known as shingles, is caused by the varicella zoster virus (VZV) and occurs in approximately one in three adults in their lifetime and incidence significantly increases at approximately 50 years of age. Protective immunity against VZV wanes as the immune system ages, allowing reactivation of the virus from latently infected neurons, causing painful and itchy lesions. Serious herpes zoster complications include postherpetic neuralgia (10-13% of herpes zoster cases), bacterial coinfections and cranial and peripheral palsies; 1-4% of individuals with herpes zoster cases are hospitalized for complications. Severity of disease and likelihood of complications, including postherpetic neuralgia (PHN) also increases with age. People with immunocompromising conditions, people with autoimmune disease using immunosuppressive therapies, people living with HIV and hematopoietic stem cell (HSCT) and organ transplant recipients have an increased risk of developing herpes zoster. The current standard of care is Shingrix, an FDA-approved vaccine for the prevention of shingles in adults 50 years and older. It is more than 90% effective against herpes zoster in adults aged 50-70 with only a slight reduction in efficacy for adults over age 70.

We are conducting an ongoing Phase 1/2, randomized, observer-blind, active-controlled, dose-ranging study to evaluate the safety, reactogenicity and immunogenicity of mRNA-1468, compared head-to-head with Shingrix, in healthy adults, aged 50 years and older. The first participant was dosed in February 2023 and enrollment of 500 participants was completed in June 2023.

HIV vaccine (mRNA-1644 and mRNA-1574)

HIV is the virus responsible for acquired immunodeficiency syndrome (AIDS), a lifelong, progressive illness with no effective cure. Approximately 38 million people worldwide are currently living with HIV, with 1.2 million in the U.S. Approximately 1.5 million new infections of HIV are acquired worldwide every year and approximately 680,000 people die annually due to complications from HIV/AIDS. The primary routes of transmission are sexual intercourse and IV drug use, putting young adults at the highest risk of infection. From 2000 to 2015, a total of $562.6 billion globally was spent on care, treatment and prevention of HIV, representing a significant economic burden.

We are developing two HIV vaccine candidates—mRNA-1644 and mRNA-1574—both of which are in ongoing Phase 1 clinical trials. In collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill & Melinda Gates Foundation, mRNA-1644 is testing a novel HIV vaccine strategy in humans as delivered by mRNA to elicit broadly neutralizing HIV-1 antibodies (bnAbs) through sequential vaccination of novel prime and boost antigens that induce specific B-cell responses. In collaboration with IAVI, Scripps, NIH and the HIV Vaccine Trials Network, mRNA-1574 is testing multiple native-like HIV trimer mRNAs in humans to improve our understanding of how to make stable and immunogenic native-HIV trimers.

Infectious disease vaccines: Vaccines against enteric viruses

Norovirus vaccines (mRNA-1403 and mRNA-1405)

Among enteric viruses, norovirus is a leading cause of diarrheal disease, also referred to as acute gastroenteritis (AGE) globally, resulting in substantial health care burden. Norovirus is estimated to be the causative agent in 18% of all AGE cases worldwide. The highest incidence globally is in young children, and in low-income countries, there are approximately 70,000 deaths annually caused by norovirus in children under 5 years of age. In high-income countries, incidence is also highest among young children, but deaths and other severe outcomes are concentrated primarily among older adults and immunocompromised patients. Norovirus is also associated with large, costly and difficult to control outbreaks in closed and semi-closed settings, such as daycares, cruise ships, long term care facilities and other healthcare settings. The burden of norovirus among older adults is expected to rise along with societal aging and an increased need for institutionalized care. In the U.S., norovirus causes an estimated 20 million infections, 100,000 hospitalizations and 900 deaths per year. Globally, there are approximately 650 million infections annually with approximately 200,000 deaths across all ages.

Norovirus has broad genetic diversity; the virus is classified into 10 genogroups and 49 genotypes, 30 of which are known to infect humans. Vaccine development has been challenging to date for many reasons, including the lack of a robust cell culture system, no reliable immune markers of norovirus protection and the broad and shifting diversity of genotypes. A multivalent vaccine with broad genotype coverage is needed to maximize protection against the genotypes most frequently associated with AGE in young children and older adults.

We are currently developing pentavalent (mRNA-1405) and trivalent (mRNA-1403) vaccine candidates for norovirus. Both candidates are in a Phase 1 study to evaluate safety, reactogenicity and immunogenicity in healthy adult participants 18 to 49 years of age and 60 to 80 years of age. Approximately 660 participants were enrolled in the Phase 1 study, and dosing was completed in December 2023.

Infectious disease vaccines: Bacterial vaccines

Lyme vaccines (mRNA-1975 and mRNA-1982)

Approximately 120,000 Lyme disease cases are reported per year in the U.S. and Europe. With rising atmospheric temperatures, Lyme territory continues to increase in the U.S. Lyme disease burden follows a bimodal age distribution, affecting mainly children under 15 and older adults. Patients can develop rash, fever, headaches, fatigue, joint pain, swelling, stiffness and headaches. Older adults appear more likely to have an unfavorable treatment response and more common neurologic manifestations as compared with younger patients. There are no approved vaccines to prevent Lyme disease in humans currently on the market.

To address Lyme's biological complexity, we are advancing a seven-valent and single-valent approach with two Lyme disease vaccine candidates being developed in parallel. mRNA-1982 is designed to elicit antibodies specific for Borrelia burgdorferi, which causes almost all Lyme disease in the U.S. mRNA-1975 is designed to elicit antibodies specific for the four major Borrelia species causing disease in the U.S. and Europe.

Both the seven-valent (mRNA-1975) and single-valent (mRNA-1982) vaccines are in a Phase 1/2, randomized, observer-blind, placebo-controlled, dose-ranging study to evaluate safety and immunogenicity in healthy participants 18 through 70 years of age. We have completed enrollment of approximately 800 participants in this study. In January 2024, the FDA granted Fast Track Designation to our Lyme disease program.

Infectious disease vaccines: Public health vaccines

Zika vaccine (mRNA-1893)

The Zika virus is a single stranded RNA virus of the Flaviviridae family. Seroepidemiology data suggest that it is endemic to regions of Africa and Asia, where the Aedes mosquito vectors are found. Zika virus is predominantly spread by mosquitos from the Aedes genus, but it can also be transmitted congenitally, sexually and through blood donation. Zika infection is usually asymptomatic or mild in adults, leading to fever, rash and conjunctivitis. However, infection of women during pregnancy can result in devastating microcephaly in newborns. Microcephaly is a birth defect characterized by an abnormally small head and brain, associated with lifelong neurodevelopmental delay, seizures, intellectual disability, balance problems and dwarfism/short stature, resulting in significant disability and requiring lifelong support. In 2007, a Zika infection outbreak progressed across the Pacific islands. An outbreak observed in Brazil in 2015 soon spread across the Americas, which led the WHO to declare Zika a public health emergency of international concern in 2016. During the period, tens of thousands of cases of microcephaly and congenital Zika syndrome were reported in infants. Zika has also been associated with certain neurological sequelae, such as Guillain-Barré syndrome, reported in adults.

Our Zika vaccine candidate, mRNA-1893, encodes for the prME structural protein encapsulated in our proprietary LNP. In partnership with BARDA, we are conducting a Phase 2 study in the United States and Puerto Rico to evaluate mRNA-1893 in approximately 800

participants. The randomized, placebo-controlled study aims to evaluate the safety, tolerability and reactogenicity of mRNA-1893, as well as evaluate the immunogenicity of two dose levels of mRNA-1893 (one-dose or two-dose schedule) compared to placebo. The study is fully enrolled. We do not anticipate advancing the Zika program into further studies in the absence of further outside funding.

Nipah vaccine (mRNA-1215)

Nipah virus (NiV) is a zoonotic virus transmitted to humans from animals, contaminated food or through direct human-to-human transmission and causes a range of illnesses including fatal encephalitis. Severe respiratory and neurologic complications from NiV have no treatment other than intensive supportive care. The case fatality rate among those infected is estimated at 40-75%. NiV outbreaks cause significant economic burden to impacted regions due to loss of human life and interventions to prevent further spread, such as the slaughter of infected animals. NiV has been identified as the cause of isolated outbreaks in India, Bangladesh, Malaysia and Singapore since 2000 and is included on the WHO R&D Blueprint list of epidemic threats needing urgent R&D action.

In collaboration with the NIH-Vaccine Research Center (VRC), we are conducting an ongoing Phase 1 clinical trial of mRNA-1215, our vaccine candidate against NiV, and testing will be focused on pandemic preparedness. This Phase 1 dose-escalation, open-label clinical trial is the first study of mRNA-1215 in healthy adults to evaluate the safety, tolerability and immunogenicity of a NiV mRNA vaccine candidate. The trial is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID).

Mpox vaccine (mRNA-1769)

Mpox is an infectious viral disease that can occur in humans and some other animals. It is caused by the monkeypox virus, a zoonotic virus in the genus Orthopoxvirus. Transmission of mpox has been associated with direct contact with bodily fluid or sores. Mpox may also be transmitted via respiratory secretion with close face-to-face contact.

The most widely known member of the Orthopoxvirus genus is Variola virus, which causes smallpox. Although smallpox was eradicated in 1977, continued protection from smallpox is of great interest given the lethality of the infection and potential for use as an agent of bioterrorism. Other diseases associated with the Orthopoxvirus genus include cowpox, horsepox and camelpox.

There are two subtypes of the monkeypox virus—Clade I and Clade II. In 2022, an outbreak of the Clade II mpox virus was declared a Public Health Emergency of International Concern by the WHO. The outbreak resulted in approximately 93,000 confirmed cases across 117 countries. More recently, the Clade I monkeypox virus, which is associated with greater mortality, has been reported to be sexual transmitted and there is concern that it may lead to further global outbreaks.

The current standard of care for mpox is Jynneos, which is approved by the FDA for the prevention of mpox and smallpox disease. Our mpox vaccine (mRNA-1769) is designed to express four antigens from the monkeypox virus to provide a range of protection.

We are conducting a randomized, placebo-controlled, dose-ranging, observer-blind Phase 1/2 study to evaluate the safety, tolerability and immunogenicity of mRNA-1769 in healthy participants.

CANCER VACCINES AND THERAPEUTICS MODALITY

Our cancer vaccines and therapeutics modality currently has three development programs, all of which have entered the clinic.

Individualized Neoantigen Therapy (INT) (mRNA-4157)

As tumors grow, they acquire mutations, some of which create new protein segments, or neoantigens, that can be presented on human leukocyte antigen (HLA) molecules in the tumor and recognized as non-self by T cells. While some of these neoantigens could be shared across tumors, the majority are completely unique to an individual patient's tumor, in addition the presentation of those neoantigens is also dependent on a patient's specific HLA type.

Our INT, mRNA-4157, uses next generation sequencing and our proprietary algorithm to design an mRNA that encodes up to 34 neoantigens against each individual patient's tumor mutations with specificity to their HLA type, and is predicted to elicit both class I (CD8) and class II (CD4) responses. The neoantigens are encoded in a single mRNA sequence and formulated in our proprietary LNPs designed for intramuscular injection. INT is manufactured using an automated workflow to enable a rapid turnaround time.

We are developing mRNA-4157 in collaboration with Merck. In September 2022, Merck exercised its option for personalized cancer vaccines, including mRNA-4157, pursuant to the terms of our existing PCV Collaboration and License Agreement with Merck, which was amended and restated in 2018 (PCV Agreement). Pursuant to the PCV Agreement, we and Merck will collaborate on further development and commercialization of mRNA-4157, and we will share costs and any profits and losses worldwide related to mRNA-4157 equally.

In December 2022, we announced that the randomized Phase 2 trial of mRNA-4157 had met its primary endpoint. The open-label Phase 2 study is investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared

to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma. The study showed that mRNA-4157 in combination with KEYTRUDA reduced the risk of recurrence or death by 44% (HR=0.56 [95% CI, 0.31-1.02]; one-sided p value=0.0266) compared with KEYTRUDA alone. The results are the first demonstration of efficacy for an investigational mRNA cancer treatment in a randomized clinical trial in melanoma. Adverse events observed were consistent with those previously reported in a Phase 1 clinical trial, which showed mRNA-4157 to be well-tolerated at all dose levels.

In February 2023, mRNA-4157 received a Breakthrough Therapy Designation from the FDA, and in April 2023 mRNA-4157 received PRIME Scheme Designation from the EMA.

In December 2023, we announced that at a planned median follow-up of approximately three years, mRNA-4157 in combination with KEYTRUDA showed sustained benefit, reducing the risk of recurrence or death by 49% (HR=0.510 [95% CI, 0.288-0.906]; one-sided nominal p=0.0095) and the risk of distant metastasis or death by 62% (HR=0.384 [95% CI, 0.172-0.858]; one-sided nominal p= 0.0077) compared to KEYTRUDA alone in stage III/IV melanoma patients with high risk of recurrence following complete resection. We and Merck have initiated Phase 3 studies in the adjuvant setting in patients with high-risk melanoma and non-small cell lung cancer (NSCLC), and plan to expand to additional tumor types.

KRAS Vaccine (mRNA-5671)

We are evaluating next steps for our KRAS vaccine program (mRNA-5671), having retained all rights to the program from Merck. Enrollment closed in the Phase 1 study led by Merck in early 2022. KRAS is a frequently mutated oncogene in epithelial cancers, primarily lung, colorectal cancer (CRC) and pancreatic cancers. mRNA-5671 is designed to present neoantigens for the four most prevalent KRAS mutations.

Checkpoint cancer vaccine (mRNA-4359)

We are developing a checkpoint cancer vaccine (mRNA-4359) that express Indoleamine $_{2,3}$-dioxygenase (IDO) and programmed death-ligand 1 (PD-L1) antigens. We designed mRNA-4359 with the goal of stimulating effector T cells that target and kill suppressive immune and tumor cells that express target antigens. Our initial indications for mRNA-4359 are advanced or metastatic cutaneous melanoma and NSCLC. Our Phase 1 study of mRNA-4359 is ongoing.

INTRATUMORAL IMMUNO-ONCOLOGY MODALITY

Our intratumoral immuno-oncology modality currently has one development program, which is in the clinic.

OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752)

Despite recent advances in immune-mediated therapies for cancer, the outlook for many patients with advanced cancer is poor. We are developing Triplet (mRNA-2752) to drive anti-cancer T cell responses by transforming cold tumor microenvironments into productive, “hotter” immune landscapes with local intratumoral therapies. mRNA-2752 utilizes the intrinsic advantage of mRNA to multiplex and to produce membrane and secreted proteins with mRNA in a single product candidate. Triplet (mRNA-2752) includes three mRNAs encoding human OX40L, IL-23 and IL-36γ that are encapsulated in our proprietary LNP and administered intratumorally. OX40L is a membrane protein, whereas IL-23 and IL-36γ are secreted cytokines. We believe our approach has the advantage of localized high concentration gradients of IL-23 and IL-36γ compared to recombinant proteins administered systemically or intratumorally. Additionally, the mRNA for OX40L encodes for the wild type membrane protein, which we believe recombinant protein technologies cannot enable.

In December 2023, we completed enrollment in our ongoing Phase 1 dose-escalation study of mRNA-2752 for the treatment of advanced or metastatic solid tumor malignancies or lymphoma (as a single agent or in combination with checkpoint inhibitors).

RARE DISEASE INTRACELLULAR THERAPEUTICS

Our rare disease intracellular therapeutics modality currently has six development programs, three of which are in the clinic.

Propionic acidemia (PA) (mRNA-3927)

PA is a rare, inherited metabolic disorder with significant morbidity and mortality, affecting one in 100,000-150,000 individuals worldwide. PA is caused by pathogenic variants in the propionyl-coenzyme A carboxylase (PCC) α or β subunits (PCCA and PCCB genes, respectively), leading to PCC deficiency and subsequent accumulation of toxic metabolites. PA is characterized by recurrent life-threatening metabolic decompensation events (MDEs) and multisystemic complications. Multisystemic complications include neurological manifestations, cardiomyopathy, arrythmias, growth retardation, recurrent pancreatitis, bone marrow suppression and predisposition to infection. Long-term, insults by toxic metabolites cause complications in various organs, and cognitive outcome is

negatively correlated with the number of MDEs. Currently, there is no approved therapy for PA that targets the underlying root cause of the disease.

Our PA therapy candidate, mRNA-3927, is a novel, IV-administered, LNP-encapsulated dual mRNA therapy that encodes for PCCA and PCCB subunit proteins to restore functional PCC enzyme activity in the liver. By encoding for intracellular proteins, mRNA therapy has a potential role in preventing and treating acute metabolic decompensations.

The global Phase 1/2 clinical trial for mRNA-3927, the Paramount Study, is ongoing and we have fully enrolled all five dose optimization cohorts, as well as a dose confirmation cohort. The objective of the study is to evaluate the safety and pharmacology of mRNA-3927 in patients 1 year of age and older with PA. The primary endpoints are safety and pharmacokinetics and pharmacodynamics. Secondary endpoints include incidence and severity of adverse events (AEs) and change in plasma biomarkers: methylcitric acid (2-MC) and 3-Hydroxypropionic acid (3-HP). We have received Rare Pediatric Disease Designation, Orphan Drug Designation and Fast Track Designation from the FDA and Orphan Designation from the European Commission for the PA program. Several critical milestones have been reached in the trial. mRNA-3927 has been generally well-tolerated to date with no drug-related serious adverse events, no discontinuations due to safety and only mild-to-moderate infusion related reactions (<10% of doses). Due to the objective and disease-defining nature of MDEs, regulators have provided initial support for MDE as a clinically meaningful, preferred primary clinical endpoint for development. Based on the preliminary data, there was a decrease in the number of MDEs post-mRNA-3927 treatment. We expect to advance mRNA-3927 into a pivotal study in 2024.

Methylmalonic acidemia (MMA) (mRNA-3705)

MMA is a rare, inherited metabolic disorder with significant morbidity and mortality caused by a deficiency in an enzyme called methylmalonyl-CoA mutase (MUT). There are an estimated 500-2,000 people with MMA MUT deficiency in the United States based on estimated birth prevalence (0.3-1.2:100,000 newborns) and mortality rates. Mortality is significant, with mortality rates of 50% for those with complete MUT deficiency (mut 0) (median age of death 2 years) and 40% for MMA patients with partial MUT deficiency (mut -) (median age of death 4.5 years) reported in a large European study. MMA mainly affects the pediatric population and usually presents in the first few days or weeks of life. The occurrence of acute metabolic decompensations is the hallmark of the disorder and decompensations are typically more frequent in the first few years of life. Each decompensation is life-threatening and often requires hospitalization and management at an intensive care unit. Survivors often suffer from numerous complications including chronic renal failure and neurologic complications such as movement disorders, developmental delays, and seizures. Consequently, the health-related quality of life for MMA patients and their families is significantly impaired. There are currently no approved therapies that address the underlying defect for MMA.

Our MMA therapy candidate, mRNA-3705, encodes for a missing or deficient hepatic enzyme. In an ongoing Phase 1/2 study, fifteen participants have been dosed. Thus far, all eligible participants have opted to participate in the Open-Label Extension study. To date, mRNA-3705 has generally been well-tolerated with no discontinuations due to safety or meeting protocol defined dose limiting toxicity criteria. Interim results demonstrated encouraging initial pharmacodynamic data, with dose-dependent reductions in methylmalonic acid in cohorts 2 and 3. Early results suggest potential promising changes in clinical endpoints. We are currently dosing our fifth cohort as we prepare to select an optimal dose for expansion. We expect to advance mRNA-3705 into a pivotal study in 2024.

Glycogen storage disease type 1a (GSD1a) (mRNA-3745)

GSD1a is a rare, inherited metabolic disorder caused by a deficiency in the catalytic activity of the intracellular protein glucose 6-phostphatase (G6Pase). GSD1a patients suffer from severe fasting hypoglycemia, hepatomegaly, nephromegaly, lactic acidemia, hypertriglyceridemia, hyperuricemia, hypercholesterolemia, hepatic steatosis and growth retardation. In addition, hepatocellular adenomas occur in 70% to 80% of GSD1a patients by their third decade of life and carries risk of transformation into hepatocellular carcinomas. Proteinuria has been observed in over half of patients above 25 years of age. GSD1a occurs in approximately 1:100,000 live births in the United States and European Union but is more common in Ashkenazi Jews where the incidence is reported to be 1:20,000 live births. There are an estimated 2,500 people in the United States and over 4,000 people in the European Union with GSD1a. Although strict diet therapy, including frequent feeding with uncooked cornstarch, allows GSD1a patients to live into adulthood by preventing hypoglycemia, the underlying pathological processes remain uncorrected resulting in the development of many long-term complications including liver adenomas and hepatocellular carcinoma.

Our GSD1a therapy candidate, mRNA-3745, consists of an mRNA encoding for modified human G6Pase, and has been granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA). A Phase 1/2 study to evaluate the safety and pharmacology of mRNA-3745 in GSD1a patients 18 years of age and older is ongoing. We have observed encouraging signs of clinical benefit with mRNA-3745.

Ornithine transcarbamylase (OTC) deficiency (mRNA-3139)

Ornithine transcarbamylase (OTC) deficiency (OTCD) is an X-linked recessive disorder that is the most common urea cycle disorders (UCDs) in humans. OTCD prevents the breakdown and excretion of ammonia, allowing ammonia to accumulate, rising to toxic levels where it affects the central nervous system. With an incidence of approximately 1:57,000 live births, OTCD accounts for nearly half of all UCDs. OTCD causes high mortality and morbidity, particularly in males.

Our OTCD therapy candidate, mRNA-3139, is in preclinical development. mRNA-3139 is a chronic intravenous, mRNA, enzyme replacement therapy for OTCD, which may act as a bridge to liver transplant or a standalone therapeutic depending on efficacy. mRNA-3139 uses the same LNP as in our GSD1a program.

Phenylketonuria (PKU) (mRNA-3210)

PKU is a rare inherited metabolic disease, affecting approximately 40,000 patients in the United States, France, Germany, Italy, Spain and the UK. Mutations in the phenylalanine hydroxylase (PAH) gene encoding the PAH enzyme result in the inability to metabolize the essential amino acid Phe to Tyr in the liver. There is a high unmet medical need for patients with PKU with early and continuous treatment throughout life being fundamental to prevent the development of irreversible neuropsychiatric outcomes.

Our PKU therapy candidate, mRNA-3210, which is in preclinical development, is an mRNA encoding the PAH enzyme encapsulated in the same LNP as that used in our MMA and PA product candidates, with the potential to address the unmet need in PKU patients.

Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351)

CN-1 is a severe condition caused by the mutations in the UGT1A1 gene. CN-1 is characterized by high levels of a toxic substance called bilirubin in the blood (hyperbilirubinemia). It is caused by mutations in the UGT1A1 gene, which results in an inability to break down bilirubin, a substance made by the liver. Without the UGT1A1 enzyme, bilirubin can build up in the body and lead to jaundice and damage to the brain, muscles and nerves. The symptoms become apparent shortly after birth and can be life-threatening. It is estimated that there are only approximately 70-100 known cases of CN-1 in the world. Affected individuals rely on current standard of care, phototherapy treatments of up to 12 hours a day, throughout life. The only definitive treatment is liver transplant, which is associated with its own set of side effects and risk of death.

Our CN-1 therapy candidate, mRNA-3351, consists of an mRNA encoding human UGT1A1 encapsulated in our proprietary LNPs. It is designed to restore the missing or dysfunctional protein that causes CN-1. We have licensed mRNA-3351 to Institute for Life Changing Medicines (ILCM) with no upfront fees and without any downstream payments. The goal of the collaboration is to make an mRNA therapy for the treatment of CN-1 available at no cost to patients. We are collaborating with the ILCM in developing a preclinical package for Investigational New Drug application and Clinical Trial Application filings. ILCM will be responsible for the clinical development of mRNA-3351.

INHALED PULMONARY THERAPEUTICS

Our inhaled pulmonary therapeutics modality currently has one product candidate.

Cystic Fibrosis (CF) (mRNA-3692/VX-522)

CF is a rare genetic disease, which is progressive from birth and leads to multi-organ damage and early death due to lung dysfunction. It is caused by the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which results in the loss of CFTR chloride ion channel function. This decreased function of CFTR at the cell surface leads to thick, sticky mucus in multiple organ systems but most pathologically the lungs. There are approximately 92,000 patients living with cystic fibrosis in the United States, Europe, Australia and Canada, with over 5,000 of these patients not being able to benefit from the approved CFTR modulators.

We are collaborating with Vertex on our CF candidate, mRNA-3692/VX-522, which is designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional CFTR protein for the treatment of the 10% of patients who do not produce any modulator-responsive CFTR protein. This would be our first demonstration of a nebulized mRNA therapy.

Vertex has initiated a Phase 1, single ascending dose clinical trial in CF patients who cannot benefit from CFTR modulators, and the FDA has granted VX-522 Fast Track designation. The trial is active and enrolling patients. Vertex expects to complete the single ascending dose study and to initiate the multiple ascending dose study.

SYSTEMIC SECRETED AND CELL SURFACE THERAPEUTICS MODALITY

Our systemic secreted and cell surface therapeutics modality currently has two active development programs, of which one has entered the clinic.

Relaxin (mRNA-0184)

Relaxin is a naturally occurring hormone that has been shown to promote vasodilation and angiogenesis, regulate extracellular matrix turnover and suppress arrhythmias post myocardial infarction. Relaxin plays an important role in women in pregnancy, but in addition, studies have pointed to its vasodilatory, antifibrotic, anti-inflammatory and other protective effects on multiple organs. There is a large body of evidence to support relaxin's clinical potential in several therapeutic areas, with its impact on cardiovascular diseases having been studied in both preclinical and clinical settings. Though prior studies have failed to demonstrate long-term benefit in clinical studies, we believe a novel approach can overcome potential flaws of previous approaches.

We are developing mRNA-0184, which encodes for a relaxin fusion protein, to treat decompensated heart failure. Acute heart failure is defined as the new onset or worsening of symptoms and signs of heart failure. In developed countries, heart failure has become a substantial public health problem, affecting 2% of the adult population and acute heart failure is the most frequent cause of unplanned hospital admission in patients over 65 years of age. mRNA-0184 encodes for the relaxin fusion protein. The mRNA sequence of mRNA-0184 is engineered to increase protein expression and prolong half-life.

In December 2022, we initiated dosing in a Phase 1 trial for mRNA-0184 and the trial is ongoing. Our Phase 1 trial is an adaptive, open-label, single ascending dose to single-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of mRNA-0184 in participants with chronic heart failure.

PD-L1 (mRNA-6981)

PD-L1 is a co-inhibitory receptor that can induce anergy in programmed cell death protein 1 (PD-1)-expressing T cells. We intend to induce expression of PD-L1 on myeloid cells to send a tolerizing signal to immune cells in their environment in order to treat autoimmune diseases.

The PD-L1/PD-1 pathway has a critical function in immune regulation and promotes development and function of regulatory T (Treg) cells. PD-L1 is a transmembrane protein expressed on antigen presenting cells, such as dendritic cells and macrophages, activated T cells, B cells and monocytes, as well as peripheral tissues. Its cognate receptor, PD-1, is a co-inhibitory transmembrane protein expressed on T cells, B cells, natural killer cells and thymocytes. Preclinical mouse models deficient in PD-1 spontaneously develop a variety of autoimmune diseases such as arthritis, myocarditis, lupus-like glomerulonephritis and type 1 diabetes, demonstrating the critical role of the PD-L1/PD-1 interaction in maintaining tolerance to self-antigens. Additionally, treatment of cancer patients with PD-1 or PD-L1 inhibitors sometimes results in immune-related adverse events, including the development of hepatitis, dermatitis and colitis, demonstrating the role of PD-1/PD-L1 in human autoimmune reactions.

We believe our PD-L1 therapy may augment PD-L1 expression on cell types similar to those that endogenously express it, and by reducing immune activation, potentially reduce the clinical manifestations of a variety of autoimmune diseases. Our intent is to use our platform to influence myeloid cells, including dendritic cells, to provide additional co-inhibitory signals by augmenting endogenous expression of PD-L1. We believe that this tolerizing signal to lymphocytes may limit autoreactivity in the context of ongoing autoimmune pathology without severe and global suppression of the immune system. Given that our platform allows us to modify myeloid cells *in situ*, our approach to the creation of a tolerogenic environment may provide unique benefits in treating autoimmune diseases by seeking to restore immune homeostasis.

After undertaking preclinical development, we determined that the current design of mRNA-6981 does not meet our criteria for advancement to the clinic. PD-L1 continues to be an area of interest, and we are currently evaluating other preclinical mRNA candidates.

MANUFACTURING

Manufacturing plays a critical role in our value chain and our ability to develop our medicines. Our manufacturing capabilities support every stage of the development of our products, from discovery to commercialization. During the research stage of product development, manufacturing provides mRNA drug substance and drug product for platform research and therapeutic area drug discovery. During early development of our product candidates, we manufacture mRNA and drug product for IND-enabling GLP toxicology studies and initial human clinical studies. For late clinical development, we produce mRNA and drug product for Phase 3 trials. At the commercial stage, we manufacture drug substance and drug product in collaboration with our contract manufacturing organizations (CMOs), both in the United States and internationally.

In 2023, as the COVID-19 vaccine market moved from a pandemic to an endemic market, we significantly resized our manufacturing infrastructure and reshaped our supply capabilities to help position our COVID-19 franchise for future profitability.

Overview of our manufacturing operating model

Our manufacturing activities generally focus on:

- **Commercial Production:** Our manufacturing capabilities include state-of-the-art technologies for mRNA and drug substance manufacturing, as well as quality control testing to attain a robust and consistent supply that matches target product profiles. Our manufacturing technology is built to scale-up and support production of products for commercial approval. Our platform allows for efficient manufacturing at scale.
- **Research and Development Support:** The product supply enables platform research and drug discovery in our therapeutic and vaccine areas, in addition to activities related to clinical studies of our product candidates.

We have built a dedicated in-house, multi-building manufacturing campus in Norwood, Massachusetts, the Moderna Technology Center (MTC). The MTC provides supply for our preclinical research, IND-enabling GLP toxicology study supplies, our Phase 1 and Phase 2 pipeline activities, later-stage clinical development activities (e.g., Phase 3 CMV vaccine clinical trials), as well as drug substance commercial production for vaccines. Our vaccine drug substance production for the U.S. market is completed at our MTC campus. The MTC has been designed to allow us to continue to optimize our mRNA products as we explore new pharmaceutical delivery forms in our manufacturing network such as prefilled syringes. The MTC campus has been designed with a high level of automation and state-of-the-art digital integration to handle manufacturing execution, product testing and release, and regulatory filings.

In the second quarter of 2023, we acquired a newly constructed, 140,000 square feet biomanufacturing facility in Marlborough, Massachusetts. The facility is currently undergoing enhancements, including the addition of 60,000 square feet. We expect the facility to be operational in 2025. This new site is strategically intended to support our INT program.

We have also announced agreements with the governments of Australia, Canada and the United Kingdom to establish state-of-the-art mRNA manufacturing facilities in those countries, pursuant to which each government has entered into a multi-year commitment to purchase mRNA products from us, once approved. We expect that these local manufacturing facilities will provide direct access to rapid pandemic response capabilities and our respiratory virus vaccine candidates. We may seek to enter into future agreements with other governments to provide similar manufacturing capabilities in other geographies.

In addition to our internal manufacturing facilities, we also maintain relationships with CMOs in the United States and abroad, providing drug substance and fill-finish capacity for our vaccines. As noted above, during the third quarter of 2023, we resized our manufacturing footprint to reduce our commitments to certain CMOs as a result of lower anticipated demand for COVID-19 vaccines in the endemic market.

Manufacturing technology development

To support our broad pipeline of products, which span multiple therapeutic areas and routes of administration, our platform research and technical development teams closely collaborate to facilitate rapid and seamless clinical translation of scientific breakthroughs. This enables us to develop potential medicines to serve a broad patient population.

Technical development encompasses the design and optimization of robust and consistent manufacturing processes, product characterization, fit-for-purpose formulations and product presentations. For instance, our novel hardware platforms' automation and robotics, coupled with the flexibility of our in-house digital development systems, allows for thousands of experiments and process parameters across our projects, thus supporting our drug product pharmaceutical readiness. Moreover, our recent technical manufacturing advances have enabled internalization of new key capabilities, including DNA plasmids and small molecules.

In parallel, we have refined existing processes, resulting in increased manufacturing scale and more robust stability profiles. These improvements allow us significant control over our supply chain, resulting in larger production yields and longer shelf life of our products. Furthermore, formulation development advancements have added new drug product images, including lyophilization, giving us a path from frozen to refrigerated storage conditions.

Our substantial investments in recent years in technical development has enabled the breadth and depth of our pipeline, and laid the foundation to help meet the needs and requirements associated with late-stage development and the commercialization of our products.

Supply of mRNA for All Stages of Product Development and Commercialization

Supply for Research

High-throughput automation and custom engineered equipment allow us to produce and deliver high quality mRNA and formulated constructs in a short period of time: our proprietary platform is capable of producing up to 1,000 lots of mRNA sequences and formulations per month with a turnaround time of a few weeks from sequence to final product. The typical scale of mRNA manufactured by this team is 1-1,000 mg. This has been possible, in part, due to the ability of researchers in the Moderna ecosystem to order constructs through an integrated digital portal that tracks materials end-to-end in less than 45 days. In addition, multiple integrated algorithms that leverage artificial intelligence and machine learning optimize manufacturability, reduce failures and increase quality of mRNA sequences.

Supply for Clinical Development

We have established manufacturing capabilities that support the early development stage of product development in three key areas: GLP Tox, Clinical Studies and INTs. We supply formulated product to conduct IND-enabling GLP toxicology studies. In addition, human clinical studies rely on supply to meet required cGMP standards. This is achieved via internal manufacturing at the MTC campus. Our MTC campus is also suited to enable rapid technology development and scale-up for future needs.

Our manufacturing also produces cGMP INTs. Due to the specialized nature of personalized medicine (i.e., where a batch is specifically designed and manufactured for a single patient), the manufacturing process for INTs has unique requirements. We digitally integrate patient-specific data from sequencing tumor samples to automatically design INTs for patients. We have developed proprietary bioinformatics designed algorithms linked to an automated manufacturing process for rapid production of formulated mRNA, with a typical turnaround time of a few weeks. We have operationalized INT manufacturing at the MTC campus to meet our Phase 1 and 2 pipeline supply needs by using single-use systems with fast “needle-to-needle” turnaround times. Unlike traditional process development, each INT batch is manufactured for a single patient and thus scaled-out (in parallel) with extensive use of automation and robotics to account for the larger number of patients involved in later phases of development and commercialization. We have shown consistent quality in our production of many patient batches, each with unique mRNA sequences. In the second quarter of 2023, we acquired a new manufacturing facility in Marlborough, Massachusetts, which we expect to support our INT program.

Our manufacturing capabilities have allowed us to build our broad pipeline of development programs, including the output required to supply related toxicological and human clinical studies. While the technology that underpins these programs is the same, each program typically requires customization based on target product profiles. These custom features range from varying molecular architecture to different routes of administration, often requiring multivalent products. All programs, with the exception of INT, require that we progressively scale up supply to meet clinical demand requirements across development phases, in addition to the necessary preparation for regulatory approval and commercial production, which demand larger batch sizes. In contrast, the INT program seeks to develop a cancer therapeutic that is designed and manufactured for a specific patient, thus increasing the number of unique batches. As we scale manufacturing output for each program, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates.

Supply for Late-Stage Development and Commercialization

As we continue to manufacture our COVID-19 vaccines, our development pipeline continues to advance to later-stage development and towards commercialization. Our platform approach allows us to continue to evolve our manufacturing suites and other capabilities at our manufacturing facilities. mRNA manufacturing is flexible and one plant can manufacture multiple vaccines and therapeutics. Our manufacturing facilities also permit us to manufacture products in parallel. For instance, we can produce drug substance and drug product for our Phase 3 CMV clinical trial while manufacturing COVID-19 drug substance in the same facilities.

Quality Unit

Quality is core to the way we operate. We seek to ensure quality at Moderna through a combination of a robust Quality Management System (QMS), our quality culture and our people. In accordance with applicable regulations, we have established, documented and implemented a QMS to assure continued compliance with the requirements therein. The QMS facilitates cGMP compliance by implementing practices that identify the various required processes, their application throughout the organization and the sequence of interaction of these processes.

The primary mode of documenting these key practices is through policies, standard operating procedures (SOPs), forms and other quality records, which include an overarching Quality Policy and Quality Manual. We have implemented measurement tools and metrics to monitor, measure, and analyze these practices to support cGMP operations, achieve planned results, and support continuous improvement. We monitor these quality metrics through formal governance processes, including Quality Management Review (QMR), to enable continuous improvement. We have also established an independent Quality Unit that fulfills quality assurance and quality control responsibilities.

Environment, Health, and Safety

We have established a global Environment, Health, and Safety (EHS) organization to foster a safe and healthy work environment with a focus on compliance and sustainability. We achieve this through a combination of training, procedures, digital data collection and reporting tools, and corporate programs that drive towards continuous improvement.

Supply Chain Unit

We have established a global supply chain to enable supply of the raw materials and components used to produce our products, consistent with clinical and preclinical demands. We have worked with our external vendors to characterize critical raw materials and to understand their impact on the quality of drug substance and formulated drug product. We also assess the quality system and performance of our external vendors and work with them to comply with regulatory requirements.

DIGITAL AND AI STRATEGY

Since our founding, we have been a digital-first company, seeking to use the power of digital information to maximize our impact on patients. mRNA is an information molecule, and our company was built on the premise that the natural flow of information in life can be used to develop medicines. Leveraging over a decade of experience developing mRNA medicines, we have built a large library of data that, combined with our platform approach and cloud-native infrastructure, positions us well to scale a digital operating model using artificial intelligence (AI).

Led by our Chief Information Officer, our digital organization partners across all Moderna functions to create an integrated AI ecosystem intended to drive performance and, ultimately, greater patient and business impact. To that end, in 2021, we launched our AI Academy, which offers cross-organization training to all of our employees on topics such as data visualization, machine learning algorithms and AI ethics. Through the AI Academy, our employees learn how to leverage AI in their specific job functions. By embedding AI across our organization, we are able to scale the value of our people and progress toward our goal of becoming a real-time AI company.

AI helps optimize each aspect of our value chain, from drug design to commercial manufacturing and beyond. At the research stage, our digital and AI infrastructure allows our scientists to design novel mRNA constructs, use AI algorithms to optimize them and order them from our high throughput preclinical scale production line. Our capabilities allow us to design mRNA, protein and LNP components with desired properties, such as reduced toxicity or increased stability. At the product development stage, AI helps to improve the efficiency of our clinical trial operations by, for example, forecasting participant enrollment and automating clinical trial data processing.

Our manufacturing processes likewise utilize the power of AI. For example, we leverage a series of fully autonomous, integrated AI algorithms in connection with manufacturing mRNA-4157, our INT candidate. Our proprietary algorithms design the specific therapy for each individual patient and optimize the timely manufacture and delivery of INT to each patient.

At the commercial stage, our digital and commercial organizations came together in 2023 to drive performance and prepare for product launches. Digital and AI are key components of our commercialization strategy, and are vital to our ability to increase our speed to market, enhance our commercial capabilities and continuously improve the quality of our products. We believe that our ability to move with both scale and speed positions us well to pursue our goals related to future product launches.

Further, as generative AI (GenAI) emerged as a transformative technology in 2023, we moved quickly to develop and launch our own internal GenAI product. Recognizing the unique value of Large Language Models (LLMs) to streamline tasks across departments, we launched our internal product in May 2023 after two weeks of development and improved it sequentially thanks to the capabilities of our updated machine learning platform Compute 4.0 for rigorous data management. Approximately 75% of our employees are

currently active users, embedding the tool into their specific functions for customized support and meaningful improvements to their everyday workflows. This rapid adoption across our company demonstrates the power of our AI-centric culture.

We believe that the integrated AI ecosystem we are building at Moderna will accelerate our mission to deliver the greatest possible impact to people through mRNA medicines.

COMMERCIAL

We are building a differentiated commercial model, with active commercial subsidiaries in key markets across North America, Europe and the Asia-Pacific region. Our growing commercial footprint provides us with local commercial teams in major markets where respiratory vaccines have high utilization rates and sales. To support the build out of our commercial activities in markets around the globe, we have hired talent with extensive pharmaceutical company experience. Our commercial teams also work with third-party distributors and other partners in countries where we do not have a direct presence. Our commercial activities are dependent on regulatory approvals and on agreements that we have made or may make in the future with strategic collaborators.

Before 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and health ministries, Gavi, on behalf of the COVAX Facility, and other international organizations. During the pandemic, these sales were characterized by a relatively limited number of customers that purchased multi-dose vials for distribution through mass vaccination campaigns. As we have transitioned to an endemic market, we have witnessed a shift in demand to single-dose presentations and pre-filled syringes. In 2023, the COVID-19 vaccine market transitioned to an endemic, seasonal commercial market, characterized particularly in the U.S. (our largest market) by a fragmented customer base, less predictability in orders, seasonality of deliveries, significantly lower demand than during the pandemic and the assumption by us of full distribution costs. The private vaccine market is also characterized by market practices regarding rebates, discounts and returns. The COVID-19 vaccine market continues to depend on many evolving factors such as medical need, viral evolution, public health authority recommendations and consumer motivation to vaccinate.

We are also advancing a broader seasonal respiratory vaccine franchise, consisting of single-agent and combination vaccines against RSV, seasonal influenza and COVID-19, which have the highest medical burden among respiratory diseases. We expect regulatory approvals beginning in the first half of 2024 for our RSV vaccine, with multiple respiratory vaccine commercial launches globally over the next several years.

As we advance our portfolio beyond respiratory diseases toward approval, we are also investing in building out our commercial capabilities for other franchises. These franchises include our latent vaccine, rare disease and oncology products, which we expect to launch in the next several years.

We are also working to establish state-of-the-art mRNA manufacturing facilities in Australia, Canada and the United Kingdom, and the government in each of these countries has entered into a multi-year commitment to purchase mRNA products from us, once approved. See "—Manufacturing" above for further detail.

THIRD-PARTY STRATEGIC ALLIANCES

Strategic alliances

We have entered into strategic alliances with a diverse group of collaborators, including pharmaceutical and biotechnology companies, government agencies, academic laboratories, foundations and research institutes with therapeutic area expertise and resources. Through our collaborations, we seek to advance our discovery and development programs, while leveraging our platform and our research and early development capabilities. We also seek to partner with and invest in companies developing other types of therapeutics, such as gene editing and cell-therapy, where we believe we can leverage our core mRNA and LNP capabilities to expand the reach of our technology.

Through certain of our strategic alliances, we share the rewards and risks of developing a new mRNA modality or program, where we may have early research data and desire a strategic collaborator to join us in advancing early development candidates within such modality into the clinic. Representative relationships and associated programs include those with Merck, for our INT programs (mRNA-4157), and Vertex, for our CF program (mRNA-3692).

We view strategic alliances as important drivers for accelerating execution of our goal of rapidly developing mRNA medicines to treat patients across a wide range of medical and disease challenges. To maintain the integrity of our platform, the terms of our strategic collaboration agreements generally provide that either we receive rights to develop and commercialize potential mRNA medicines that we design and manufacture or our strategic collaborators receive rights to develop and commercialize potential mRNA medicines that we design and manufacture, as opposed to granting rights to our strategic collaborators to use our platform to generate new mRNA technologies, and that we generally own intellectual property related to our platform arising from research activities performed under

the strategic alliance. We plan to continue to identify potential strategic collaborators who can contribute meaningful technology and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

Below are brief descriptions of certain of our ongoing collaborations. In the fourth quarter of 2023, our Strategic Collaboration and License Agreement with Vertex (the Vertex 2020 Agreement) was concluded and terminated in accordance with the terms of the agreement. The Vertex 2020 Agreement had been aimed at the discovery and development of potential medicines to treat cystic fibrosis (CF) with gene-editing therapies. For additional information on this collaboration, please see Note 5. *Collaboration Agreements*, to our consolidated financial statements included in this Annual Report on Form 10-K.

Merck—Strategic Alliance for Individualized Neoantigen Therapies

In June 2016, we entered into a Collaboration and License Agreement with Merck for the development and commercialization of personalized mRNA cancer vaccines (also known as INTs), which was subsequently amended and restated in 2018 (the INT Agreement), to develop and commercialize INTs for individual patients using our mRNA vaccine and formulation technology. Under the strategic alliance, we identify genetic mutations present in a particular patient's tumor cells, synthesize mRNA for these mutations, encapsulate the mRNA in one of our proprietary LNPs and administer to each patient a unique INT designed to specifically activate the patient's immune system against her or his own cancer cells.

Pursuant to the INT Agreement, we received an upfront payment of $200 million from Merck and we were responsible for designing and researching INTs, providing manufacturing capacity and manufacturing INTs and conducting Phase 1 and Phase 2 clinical trials for INTs, alone and in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget.

In September 2022, Merck exercised its option for INTs, including mRNA-4157, pursuant to the terms of the INT Agreement and in October 2022 paid us an option exercise fee of $250 million. Pursuant to the INT Agreement, we and Merck have agreed to collaborate on further development and commercialization of INTs, and we will share costs and any profits or losses worldwide equally.

Vertex—2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement (Vertex Agreement) with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited (together, Vertex). The Vertex Agreement is aimed at the discovery and development of potential mRNA medicines for the treatment of CF by enabling cells in the lungs of people with CF to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) proteins.

Other Collaborations

In September 2020, we entered into a collaboration with Chiesi Farmaceutici S.p.A. (Chiesi), an international research-focused healthcare group, aimed at the discovery and development of mRNA medicines for the treatment of pulmonary arterial hypertension (PAH), a rare disease characterized by high blood pressure in the arteries of the lungs. Under the terms of the Chiesi agreement, we will lead discovery efforts, and Chiesi will lead development and worldwide commercialization activities and will fund all expenses related to the collaboration.

We have entered into additional collaborations where we have agreed to provide funding in areas where we believe we can leverage our mRNA technology. These collaborations include those with:

- **Carisma Therapeutics**, to discover, develop and commercialize *in vivo* engineered chimeric antigen receptor monocyte (CAR-M) therapeutics for the treatment of cancer, including solid tumors.
- **CytomX Therapeutics**, to create investigational mRNA-based conditionally activated therapies utilizing our mRNA technologies and CytomX's Probody platform.
- **Generation Bio Co.**, to combine our biological and technical expertise with core technologies of Generation Bio's non-viral genetic platform.
- **Immatics N.V.**, to pioneer novel and transformative therapies for cancer patients with high unmet medical need.
- **Life Edit Therapeutics**, to discover and develop *in vivo* mRNA gene editing therapies.
- **Metagenomi**, focused on discovering and advancing new gene editing systems for *in vivo* human therapeutic applications.

We have made equity investments in Carisma, Generation Bio and Metagenomi pursuant to those collaborations.

Strategic alliances with government organizations and foundations

Defense Advanced Research Projects Agency (DARPA)

In September 2020, we entered into an agreement with DARPA to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics.

Biomedical Advanced Research and Development Authority (BARDA)

In September 2016, we received an award of up to approximately $126 million, subsequently adjusted to $117 million in 2021, from BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), to help fund our Zika vaccine program. In September 2022, the performance period of the grant expired, and BARDA was released of the obligation to fund the remaining $36 million of the award.

In April 2020, we entered into an agreement with BARDA for an award of up to $483 million to accelerate development of mRNA-1273, our original COVID-19 vaccine. The agreement has been subsequently amended to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials, adolescent clinical trials and pharmacovigilance studies. The maximum award from BARDA, inclusive of all amendments, was approximately $1.8 billion. All contract options have been exercised. As of December 31, 2023, the remaining available funding, net of revenue earned was $97 million.

Institute for Life Changing Medicines (ILCM)

In September 2021, we entered into a collaboration agreement with the ILCM to develop a new mRNA therapeutic (mRNA-3351) for type 1 Crigler-Najjar syndrome (CN-1). Under the terms of the agreement, we agreed to license mRNA-3351 to ILCM with no upfront fees, and without any downstream payments. ILCM will be responsible for the clinical development of mRNA-3351.

The Bill & Melinda Gates Foundation

In January 2016, we entered a global health project framework agreement with the Bill & Melinda Gates Foundation to advance mRNA development projects for various infectious diseases. The Bill & Melinda Gates Foundation has committed up to $20 million in grant funding to support our initial project related to the evaluation of antibody combinations in a preclinical setting as well as the conduct of a first-in-human Phase 1 clinical trial of a potential mRNA medicine to help prevent HIV infections. Follow-on projects, which could bring total potential funding under the framework agreement up to $100 million (including the HIV antibody project) to support the development of additional mRNA projects for various infectious diseases, can be proposed and approved until the sixth anniversary of the framework agreement, subject to the terms of the framework agreement, including our obligation to grant to the Bill & Melinda Gates Foundation certain non-exclusive licenses.

INTELLECTUAL PROPERTY

We rely on a combination of intellectual property laws, including patent, trademark, copyright and trade secret, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights.

Protecting our platform, modality and program investments: Building an expansive, multi-layered IP estate

We have built a substantial IP estate that includes numerous patents and patent applications related to the development and commercialization of mRNA vaccine and therapeutic development candidates, including related platform technologies. Our platform IP protects advances in mRNA design and engineering, proprietary LNP components, delivery systems, processes for the manufacture and purification of drug substances and products and analytical methods. A significant portion of our platform IP estate further provides multi-layered protection for our modalities and programs.

With respect to our IP estate, our solely-owned patent portfolio consists of more than 230 issued or allowed U.S. patents or patent applications and more than 170 granted or allowed patents in jurisdictions outside of the U.S. (including granted European patents that have been validated in numerous European countries) covering certain of our proprietary platform technology, inventions and improvements, and covering key aspects of our clinical and most advanced development candidates. We have over 400 additional pending patent applications that, in many cases, are counterparts to the foregoing U.S. and foreign patents.

Most of the patents and applications (if issued) in our portfolio will not expire until 2033 at the earliest. Any patent that may issue from our most recently filed patent applications is projected to expire between 2042 and 2043, at the earliest. We file additional U.S. and foreign patent applications as necessary to protect our evolving intellectual property positions.

We also rely on trademarks, copyright, trade secrets and know-how relating to our proprietary technology and programs, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of mRNA therapeutic and vaccine technologies. We take additional steps, such as entering into confidentiality and license agreements, to protect our intellectually property and proprietary rights. We additionally plan to rely on data exclusivity, market exclusivity and patent term extensions when and where available, and plan to seek and rely on regulatory protection afforded through orphan drug designations. We also possess substantial proprietary know-how associated with related manufacturing processes and expertise.

IP protecting our platform

We have a broad IP estate covering key aspects of our platform. This estate provides multiple layers of protection covering the making and use of the mRNA drug substance and delivery technologies.

With respect to our platform, we have a portfolio that includes U.S. and foreign patents or patent applications covering platform innovations that are related to the design, manufacturing and formulating of mRNA medicines. For example, these patents and patent applications include claims directed to:

- mRNA chemistry imparting improved properties for vaccine and therapeutic uses;
- methods for mRNA sequence optimization to enhance the levels and fidelity of proteins expressed from our mRNA medicines;
- methods for identifying epitopes having superior suitability in cancer vaccine contexts;
- engineering elements tailored to enhance stability and the *in vivo* performance of mRNA medicines;
- LNP delivery systems, including novel lipid components designed for optimal delivery and expression of both therapeutic and vaccine nucleic acids, in particular, prophylactic infectious disease and cancer vaccine nucleic acids, intratumoral immuno-oncology therapeutics, local regenerative therapeutics, systemic therapeutics, and inhaled pulmonary therapeutics; and
- innovative processes for the manufacture and analysis of mRNA drug substance and formulated drug product.

IP protection

Our IP estate provides protection for the multiple programs both at the product-specific level and at various broader levels. For example, we have patent coverage for LNP-encapsulated mRNAs having specific chemical modification suited for vaccine and therapeutic mRNA use. Our estate also includes IP covering certain LNP-encapsulated mRNAs coding for infectious disease antigens for use in preventing or treating infectious diseases, including those caused by respiratory and latent viruses, as well as bacterial, viral and parasitic diseases known to threaten public health. Our mRNA chemistry, formulation and manufacturing patent applications and related know-how, along with trade secrets, may also provide us with additional IP protection relating to our development candidates.

Respiratory vaccines

For our respiratory vaccines programs, we have pursued patent protection featuring composition of matter and method of use claims. Where we may pursue patent protection may vary based on the unique geographic prevalence of various infectious diseases.

We have filed several patent applications covering our betacoronavirus vaccine program. We are pursuing patent protection for both our existing and next generation betacoronavirus vaccines. A non-exhaustive list of granted patents covering our COVID-19 vaccine can be found in the following table.

Patent Number	Country/Region*	Patent Type	Expiration Date**
11,524,023	United States	Composition of Matter	October 22, 2041
11,485,972	United States	Composition of Matter	May 18, 2038
10,898,574	United States	Composition of Matter and Method of Use	April 2, 2032
10,703,789	United States	Composition of Matter	March 9, 2033
10,702,600	United States	Composition of Matter	October 21, 2036
10,577,403	United States	Composition of Matter	March 9, 2033
10,442,756	United States	Composition of Matter	September 16, 2036
10,266,485	United States	Composition of Matter	September 16, 2036
10,064,959	United States	Composition of Matter	October 3, 2031
9,868,692	United States	Composition of Matter	September 16, 2036
3 590 949	Europe	Composition of Matter and Method of Use	October 3, 2031
3 718 565	Europe	Composition of Matter	October 21, 2036

* Selected granted patents in the U.S. and Europe only. Additional granted and pending patents in the U.S., Europe and other countries may be available.
** Expiration dates listed here include any granted or anticipated patent term adjustment (PTA), but not any patent term extension (PTE) or supplementary protection certificates (SPC).

RSV

We have filed multiple patent families directed to RSV vaccines, including a U.S. patent that issued on October 11, 2022. Our RSV patent portfolio includes multiple families of differing patent breadth. At least four U.S. and European patent applications are pending.

Influenza

We have multiple patent families spanning different levels of breadth, design and antigen valency pending in the U.S., Europe and around the world, including several granted patents.

hMPV

Human metapneumovirus (hMPV) is a single-stranded RNA virus that is used in a combination program. We have patent applications covering our hMPV vaccine pending in the U.S. and Europe, with a granted patent in the U.S.

Latent vaccines

We have vaccine programs and patent applications directed to both the acute and latent forms of diseases caused by various viruses, including CMV, EBV, HSV, VZV and HIV, using both preventative vaccines targeting the acute phase and therapeutic vaccines for treating the latent diseases in those who do become infected.

CMV

The patent coverage for our human CMV vaccine candidate is extensive and is based on a vaccine with six mRNAs encoding a pentamer surface glycoprotein complex and the gB surface glycoprotein. Both pentamer and gB facilitate entry of the virus into different cell types and therefore immune responses targeting these proteins can block virus entry, spread and reactivation. The current patent portfolio contains both compositions of matter and methods of treating subjects using the vaccine. In the U.S., our CMV vaccine is covered by multiple issued U.S. patents of differing breadth. Each family has counterparts consisting of pending applications and issued patents in non-U.S. jurisdictions, including Europe and Japan. A separate family of CMV patents, which includes mRNA-1647 plus mRNA-1443 for use in CMV vaccines for transplant indications, is also yielding patents and applications in foreign jurisdictions are pending.

EBV, HSV and VZV

Similar to CMV, we have multiple patent families pending for each of EBV, HSV and VZV, covering both prophylactic and therapeutic indications. These patent families have also been filed in Europe and Japan.

Public health vaccines

We maintain a multi-program effort at developing vaccines for potential future pandemics and for use in parts of the world with less well-established health care systems. This group of programs include infectious diseases such as flaviviruses such as Zika and dengue

viruses, HIV, Nipah virus, and the Mpox virus. In addition, programs are ongoing in many bacterial diseases. Specific patent families are being filed on most potential public health programs where possible, but in some scenarios, platform patents may be used to augment patent protection for public health target vaccines.

Individualized neoantigen therapy (INT)

Composition of matter and method claims are being pursued to protect programs within our cancer vaccines modality. Proprietary methods around the making and therapeutic use of our INTs and resulting vaccine compositions are described and claimed in seven pending U.S. patent applications, six pending European patent applications, five pending patent applications in Japan, three pending patent applications and one granted patent in China, and several pending patent applications in New Zealand, South Africa, Asian and South American countries, as well as one PCT application. These applications also relate to various vaccine design formats, in particular, polyepitopic vaccine formats, and methods of treating cancer with such INTs. We also possess substantial know-how and trade secrets relating to the development and commercialization of our cancer vaccine programs, including related manufacturing process and technology.

Likewise, our KRAS antigen cancer vaccine and methods of treating cancer featuring such vaccines are covered in an issued U.S. patent, which includes claims to LNP-encapsulated mRNA encoding mutant KRAS antigens.

Intratumoral immuno-oncology

We have filed numerous patent applications featuring claims to mRNAs encoding immune-stimulatory proteins and methods of treating cancer using such compositions.

Our immuno-oncology programs are designed to be administered intratumorally to alter the tumor microenvironment in favor of mounting an immune response against tumors. Our mRNA program that includes mRNAs that encode OX40L, IL-23 and IL-36γ are covered by two granted European patents, by more than 10 issued U.S. patents, by several pending U.S. and European patent applications and by several pending patent applications in other foreign jurisdictions. These applications feature claims to the mRNA therapeutics as compositions of matter, formulations that include such mRNAs and methods of reducing tumors and treating cancer using these development candidates.

Rare diseases

We have programs featuring expression of therapeutic proteins, e.g., intracellular enzymes for the treatment of rare diseases. For our rare disease programs, we generally pursue patent protection featuring composition of matter and method of use claims, for example, pharmaceutical composition and method of treatment claims. Our most advanced rare disease development candidate is for PA. For this candidate, we have patent applications pending in the United States, Europe, and Japan which cover mRNA encoding the alpha and beta subunits of the enzyme propionyl-CoA carboxylase (PCCA and PCCB, respectively), for the treatment of PA.

For MMA, we have patent applications issued and pending in the U.S. and foreign applications filed in Japan and Europe.

For our PKU development candidate, we have a pending PCT and pending patent applications in the U.S., Europe and Japan covering mRNA encoding phenylalanine hydroxylase (PAH) for the treatment of PKU.

For our Glycogen Storage Disorder, Type 1a (GSD1a) development candidate, we have filed several patent families, including pending U.S. and European patent applications, as well as applications pending in China and Japan covering mRNA encoding glucose 6-phosphatase (G6Pase) for the treatment of this disorder.

For our Crigler-Najjar Syndrome Type 1 (CN-1) development candidate, we have patent applications pending in the U.S., Europe and Japan.

Our ornithine transcarbamylase deficiency (OTC) development candidate is covered by a pending PCT application.

Any U.S. and foreign patents that may issue from these patent families would be expected to expire in 2036 for the earliest of the MMA patents and 2038 to 2042 for the remaining MMA, PA, PKU, GSD1a and CN-1 patents, excluding any patent term adjustments, any patent term extensions and any terminal disclaimers.

As further described below, we have filed or intend to file patent applications on these and other aspects of our technology and development candidates, and as we continue the development of our intended products, we plan to identify additional means of obtaining patent protection that would potentially enhance commercial success, including protection for additional methods of use, formulation, or manufacture.

Systemic secreted and cell-surface therapeutics

Our systemic secreted and cell-surface therapeutics modality features programs directed to expression of secreted or cell-surface proteins including antibodies, circulating immune modulation factors, secreted enzymes and transmembrane proteins.

Our Relaxin development candidate is covered by several patent families, including granted patents in Japan, China and the U.S., and by additional applications in the U.S. and additional foreign jurisdictions and a pending PCT application.

Our PD-L1 development candidate is covered in pending patent applications filed in the U.S., Japan and Europe.

Inhaled pulmonary therapeutics

Our inhaled pulmonary therapeutics modality currently has one development candidate directed to expression of therapeutic protein in the lungs. This Cystic Fibrosis (CF) development candidate is covered by pending U.S., European and PCT patent applications.

Gene editing

Our gene editing program currently has one filed patent family that includes issued patents in the U.S., Europe and Japan, and also pending applications in these jurisdictions. We plan to file patent applications on development candidates and other aspects of gene editing technology as we continue to innovate both internally and through strategic collaborations.

Trademarks

Our trademark portfolio currently contains at least 1,000 trademark registrations, including at least 22 registrations in the United States and the remaining in Canada, the European Union, the United Kingdom, Israel, China, Japan, Australia, and elsewhere. In addition, we have at least 600 pending trademark applications in more than 95 jurisdictions, including in the aforementioned locations and additional countries throughout Africa, Asia, and South America.

In-licensed intellectual property

While we develop and manufacture our potential mRNA medicines using our internally created mRNA technology platform, we also seek out and evaluate third party technologies and IP that may be complementary to our platform.

Patent sublicense agreements with Cellscript and mRNA RiboTherapeutics

The Trustees of the University of Pennsylvania owns several issued U.S. patents, granted European patents and pending U.S. patent applications directed, in part, to nucleoside-modified mRNAs and their uses (the Penn Modified mRNA Patents). mRNA RiboTherapeutics, Inc. (MRT) obtained an exclusive license to the Penn Modified mRNA Patents and granted its affiliate, Cellscript, LLC (Cellscript), a sublicense to the Penn Modified mRNA Patents in certain fields of use.

In June 2017, we entered into two sublicense agreements, one with Cellscript, and one with MRT, which agreements we collectively refer to as the Cellscript-MRT Agreements. Together, the Cellscript-MRT Agreements grant us a worldwide, sublicensable sublicense to the Penn Modified mRNA Patents to research, develop, make, and commercialize products covered by the Penn Modified mRNA Patents (licensed products), for all *in vivo* uses in humans and animals, including therapeutic, prophylactic, and diagnostic applications. The Cellscript-MRT Agreements are non-exclusive, although Cellscript and MRT are subject to certain time restrictions on granting additional sublicenses for *in vivo* uses in humans under the Penn Modified mRNA Patents. The Cellscript-MRT Agreements require us to pay royalties based on annual net sales of licensed products at rates in the low single digits for therapeutic, prophylactic, and diagnostic uses, and royalties based on annual net sales of licensed products sold for research uses at rates in the mid-single digits, subject to certain reductions, with an aggregate minimum floor.

The Cellscript-MRT Agreements will terminate upon the expiration or abandonment of the last to expire or become abandoned of the Penn Modified mRNA Patents. Cellscript or MRT, as applicable, may terminate its respective Cellscript-MRT Agreement if we fail to make required payments or otherwise materially breach the applicable agreement, subject to specified notice and cure provisions. Cellscript or MRT, as applicable, may also terminate the applicable Cellscript-MRT Agreement upon written notice in the event of our bankruptcy or insolvency or if we challenge the validity or enforceability of the Penn Modified mRNA Patents. We have the right to terminate each Cellscript-MRT Agreement at will upon 60 days' prior notice to Cellscript or MRT, as applicable, provided that we cease all development and commercialization of licensed products upon such termination. If rights to MRT or Cellscript under the Penn Modified mRNA Patents are terminated (e.g., due to bankruptcy of MRT or Cellscript), the terminated party will assign its interest in the respective Cellscript-MRT Agreement to the licensor from which it received rights under the Penn Modified mRNA Patents and our rights will continue under the new licensor.

Patent license agreement with NIAID

In December 2022, we entered into a non-exclusive patent license agreement with the National Institute of Allergy and Infectious Diseases (NIAID), an Institute or Center of the National Institutes of Health (NIH) to license certain patent rights concerning stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products. Pursuant to the agreement, we have agreed to pay low single-digit royalties on future net sales, a minimum annual royalty payment and certain contingent development, regulatory and commercial milestone payments on a licensed product-by-licensed product basis.

Formulation technology in-licenses

Our development candidates use internally developed formulation technology that we own. We do, however, have rights to use and exploit multiple issued and pending patents covering formulation technologies under licenses from other entities. If in the future we elect to use or to grant our strategic collaborators sublicenses to use these in-licensed formulation technologies, we or our strategic collaborators may be liable for milestone and royalty payment obligations arising from such use. We consider the commercial terms of these licenses and their provisions regarding diligence, insurance, indemnification and other similar matters, to be reasonable and customary for our industry.

HUMAN CAPITAL

We had approximately 5,600 full-time employees in 19 countries around the world as of December 31, 2023. We operate in a highly competitive environment for talent, particularly as we seek to attract and retain talent with experience in the biotechnology and pharmaceutical sectors. Our workforce is highly educated, and as of December 31, 2023, 41% of our employees hold Ph.D., Doctorate, M.D., J.D. or Master's degrees. Among our employees, as of December 31, 2023, 49% are female. Among our leadership (which we define as employees at the vice president level and above), as of December 31, 2023, approximately 39% are female. 45% of our U.S. employees identify as racially or ethnically diverse as of December 31, 2023, an increase from the prior year. In 2023, for the second year in a row, an outside statistical pay equity analysis confirmed zero statistically significant differences in pay across gender globally and across gender, race and ethnicity in the United States.

Our focus on belonging, inclusion and diversity

We are committed to building a culture of inclusion and belonging for all. In 2023, we continued to act on our commitment to belonging, inclusion and diversity by, among other things:

- continuing our monitoring and reporting of company-wide gender and ethnicity data;
- including a belonging, inclusion and diversity focus in every employee engagement survey;
- continuing to invest in our Employee Resource Groups, which are voluntary, employee-led groups that harness the power of belonging in service to our people, our company and the community at large, including by introducing mCARE, a group dedicated to supporting and empowering our employees who are caregivers and parents;
- receiving recognition from Disability:IN Inclusion and the American Association of People with Disabilities as a best place to work for Disability Inclusion; and
- conducting diversity-related events, celebrations and learning opportunities for all employees throughout the year.

Our approach to attracting and retaining talent

We are committed to ensuring that our employees find that their careers at Moderna are filled with purpose, growth and fulfillment. We believe that a career at Moderna provides opportunity for:

- **Impact**: Our people will have the opportunity to do work that is unparalleled in terms of its innovation and scope of impact on people's lives.
- **Growth**: We provide incredible opportunities for growth and we obsess over learning (as demonstrated, in part, by our Mindsets (see below). We invest substantially in the development of our people.
- **Well-being**: We are committed to the health and well-being of our employees and their families and provide numerous family-friendly benefits and opportunities to be healthy, including monthly contributions to employee lifestyle spending accounts.
- **Inclusion**: We believe in the benefits of bringing together a diverse set of perspectives and backgrounds, and creating an environment where differences are celebrated and leveraged. We measure and hold management accountable to creating an environment of psychological safety.
- **Compelling rewards**: To attract and retain the best talent, we provide competitive rewards that help to drive groundbreaking work and allow employees to share in the value we will create together, including through our equity programs.
- **Giving and volunteering:** Our people have the opportunity to give back to their communities and directly support causes that they are passionate about through volunteer and employee matching donation programs.

To help promote alignment between our employees and our shareholders, all employees participate in our corporate equity programs through the receipt of equity awards, and the percentage of equity as a component of overall pay mix increases with seniority. We also allow our employees to select how they want the value of their award to be split between stock options and restricted stock units (RSUs). We believe that in addition to incentivizing growth that leads to shareholder value, broad eligibility for our equity programs further embeds our "We behave like owners" mindset and helps promote employee retention as these awards generally vest over a four-year period.

None of our employees are represented by a labor union or works councils, and none of our employees have entered into a collective bargaining agreement with us. A small number of employees in France, Italy and Spain are covered by statutory collective bargaining agreements governing certain benefits and working conditions. We consider our employee relations to be good.

We believe that our employees are highly engaged, and our company and team have been publicly recognized for our leadership, innovation and good corporate citizenship. *Science* magazine ranked us as a top employer for each of the last nine years. Additionally, in 2023, *Biospace* ranked us the number one large employer in its 2024 Best Places to Work in Biopharma report for the third consecutive year. We also received a perfect score from the Human Rights Campaign's Equality Index for 2023-2024. We measure employee engagement through a vendor-supplied engagement software, using validated external benchmarks to track employee engagement factors.

We continually monitor employee turnover rates, as our success depends upon retaining our highly trained personnel. We believe that the competitive compensation we offer, along with the combination of the factors listed above, among other factors, have helped reduce voluntary turnover. In 2023, our voluntary turnover rate was approximately 6%.

Our approach to training our employees

To further invest in our teams, we have established a structured training curriculum for our employees so that every employee becomes deeply familiar with our core technology and technologies that might further enable our innovation. In addition, we are focused on creating strong leaders through various management and leadership trainings. We have also built an online library of videos of a variety of scientific material that our employees can access flexibly. This content includes presentations by external speakers at in-house scientific seminars, scientific courses at external universities and peer-to-peer video series in which in-house experts provide an introductory view of complex topics they tackle within their teams.

New employees participate in our Moderna ONE onboarding program, which is an interactive learning experience designed to immerse our people in our culture and Mindsets from day one. Following onboarding, our employees continue to learn throughout their careers at Moderna and we deploy a digital learning management system to track and administer training programs for each of employee.

In December 2021, we launched our Artificial Intelligence (AI) Academy in partnership with Carnegie Mellon University. The AI Academy is intended to educate and empower our employees to identify and integrate AI and machine learning solutions into every Moderna system and process to bring mRNA medicines to patients.

Our culture

As an organization, we are bold, collaborative, curious and relentless. These values are underpinned by a core set of what we call “basecamp” values— integrity, quality, respect. Additionally, with the continued rapid growth of our company, we articulated the Moderna Mindsets, which define how we behave, lead and make decisions. We believe our Mindsets will be integral to our future success, and we integrate them into every facet of how we identify, onboard, grow and manage our talent.

To further develop and retain our workforce, we conduct periodic talent reviews that identify key talent within the organization. We use that data to inform specific development opportunities for key current and potential future leaders, and to support our periodic succession planning activities for key roles. These steps together ensure we have a robust understanding of our workforce and a talent pipeline to grow future leaders, and provide our employees an opportunity to continuously grow and advance in a way that meets their aspirations and talents.

CORPORATE SOCIAL RESPONSIBILITY

As we pursue our mission to deliver the greatest possible impact to people through mRNA medicines, we have developed a corporate social responsibility (CSR) program that demonstrates our commitment to patients, employees, the environment and local communities. Our CSR framework consists of five key focus areas: medicines for patients, community, governance and ethics, employees and environment. Please refer to our 2022 ESG Report under the "Responsibility—Corporate policies" section of our website, which can be found at www.modernatx.com/responsibility/corporate-policies, as well as our proxy statement related to our 2024 Annual Meeting of Stockholders that we will file with the SEC, for a description of some of the measures we have taken to progress our commitment to corporate social responsibility.

COMPETITION

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. There is also a strong emphasis on defense of intellectual property and proprietary products.

mRNA Medicines

We believe that mRNA as a medicine coupled with our capabilities across mRNA technology, drug discovery, development and manufacturing provide us with a competitive advantage. However, we face competition from others developing mRNA vaccines and therapeutics, as well as other medicines that compete or could compete with our products. We face competition from various sources, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies and public and private research institutions. The continued growth of the mRNA field is leading to increased competitive pressure, including from large and more established pharmaceutical companies. We also face competition when entering into strategic alliances to advance and grow our pipeline.

Our COVID-19 vaccine largely competes against Pfizer/BioNTech's COVID-19 vaccine, which is also based on mRNA technology. We also compete against other approved or authorized products, including Novavax's COVID-19 vaccine. Additionally, some competitors have developed COVID-19 treatments, including Pfizer's antiviral pill, and the existence of such treatments may reduce demand for vaccines.

Competition for the sale of our COVID-19 vaccine is impacted by many factors, including, among others, actual and perceived vaccine efficacy (including against emerging SARS-CoV-2 variants), safety and tolerability, perceptions of mRNA technology, storage and handling conditions and the relative ease of distribution and administration, the timing and scope of regulatory approvals, reimbursement coverage and production and distribution costs. The competitiveness of our COVID-19 vaccines in the future may also depend on whether we successfully produce combination respiratory vaccines, which would combine in a single shot protection against various respiratory diseases, such as seasonal flu, RSV and COVID-19.

Our RSV vaccine, which we expect to launch in 2024, will face competition from existing RSV vaccines, including those produced by Pfizer and GlaxoSmithKline. We are also developing a seasonal flu vaccine, for which there is an existing, well-developed market.

In markets that we enter after competitors have already introduced a competing product, we may have difficulty achieving market share. See "Risk Factors—The pharmaceutical market is intensely competitive, and we may not compete effectively in the market for existing products, new treatment methods and new technologies."

There are additional companies working on mRNA medicines, some of which have reached commercialization. These companies include BioNTech and Pfizer (alone and in partnership with BioNTech, Beam Therapeutics and others). Others include Sanofi, GlaxoSmithKline and CureVac.

Our Collaborations

We and our strategic collaborators face competition from companies developing therapies in various areas, other than the development of mRNA medicines, related to our collaborations. For example, there are a growing number of pharmaceutical, biotechnology and academic institutions researching and developing autologous and allogeneic CAR-T therapies in both the solid and liquid tumor setting. These CAR-T cell therapies are at various stages of development and approval and could compete against any CAR-M therapeutics we discover, develop and commercialize in collaboration with Carisma Therapeutics.

Similarly, there are many companies and institutions researching and developing other nucleic acid and genetic medicines, which could compete against any therapies for genetic diseases we develop and commercialize in collaboration with Metagenomi or other collaborators.

Our Growing Commercial Footprint

Our commercial organization was established in 2020 and we have less commercial experience than many of our competitors. We are still growing our commercial footprint, and compete against other companies that have certain competitive advantages over us. See "Risk Factors—Risks related to commercialization and our products."

GOVERNMENT REGULATION

Government authorities in the United States at the federal, state and local level and in other countries and regions, such as in the European Union (EU) regulate, among other things, the research, development, manufacture and marketing of our products. Generally, before a new medicine can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained and submitted for review and approved by the competent regulatory authority.

U.S. drug and biological product development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations and biologics under the FDCA, the Public Health Service Act (PHSA), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. Failure to comply with applicable U.S. requirements at any time during the product development process, approval process or following approval may subject us to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, license revocation, a clinical hold, untitled or warning letters, product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

Any of our product candidates must be approved by the FDA through a BLA or new drug application (NDA), or supplemental BLA or supplemental NDA, process before they may be legally marketed in the United States.

Preclinical studies

Before any of our development candidates may be tested in humans, the development candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Unless the FDA raises concerns, an IND automatically becomes effective 30 days after receipt by the FDA. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials

The clinical stage of development involves the administration of the investigational medicine to healthy volunteers or patients under the supervision of qualified investigators and in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an Institutional Review Board (IRB) for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to clinical trial subjects and monitors the clinical trial until completed. Further, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. Information about certain clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

Under the U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. While the NIH Guidelines are only mandatory for research being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data.

Clinical trials generally are conducted in three sequential phases, which may overlap:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients to assess the metabolism, pharmacologic action, side effect tolerability, and safety of the investigational medicine.
- Phase 2 clinical trials generally involve disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of disease-affected patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the investigational medicine for its intended use, its safety in use and to establish the overall benefit/risk relationship of the investigational medicine, and provide an adequate basis for product labeling.

The FDA may also require post-approval Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of a drug.

The FDA or the clinical trial site may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

FDA review process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA or NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. A BLA is a request for approval to market a biologic for one or more specified indications and must contain proof of the biologic's safety, purity, and potency. An NDA for a new drug must contain proof of the drug's safety and efficacy. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA or NDA must be obtained before a biologic or drug may be marketed in the United States.

Before approving a BLA or NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee of expert advisors for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The committee makes a recommendation to the FDA that is not binding but is generally followed.

After the FDA evaluates a BLA or NDA, it will grant marketing approval, request additional information or issue a complete response letter (CRL) outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data, for the FDA to reconsider the BLA or NDA. Even if such additional information and data are submitted, the FDA may decide that the BLA or NDA still does not meet the standards for approval. If the FDA grants approval, it issues an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in very limited circumstances, such as if the latter product is shown to be clinically superior to the orphan product.

Expedited development and review programs

The FDA may employ one of several tools to facilitate and expedite the development and review of a medicine, including fast track designation, breakthrough therapy designation, accelerated approval and priority review designation. Fast track designation is designed to facilitate the development and review of a medicine that treats a serious condition and fills an unmet medical need. Breakthrough therapy designation is designed to expedite the development and review of a medicine that treats a serious condition and preliminary clinical evidence demonstrates substantial improvement over available therapies. Priority review designation means the FDA's goal is to take action on an application within six months of filing. The FDA may grant priority review designation to a medicine that would provide significant improvement in the safety or effectiveness of a treatment, diagnosis or prevention of a serious condition.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, such product must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials with due diligence. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Additionally, under FDORA, the FDA has increased authority for expedited procedures to withdraw its accelerated approval for such drug or biologic if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or that the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval.

Emergency Use Authorization (EUA)

The Secretary of Health and Human Services (HHS) may authorize unapproved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. The COVID-19 pandemic has been designated as such an emergency. After an emergency has been announced, the Secretary of HHS may authorize the issuance of and thereafter, the FDA Commissioner may issue EUAs for the use of specific products based on certain criteria, including that the product may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. The FDA may revoke an EUA for a variety of reasons, including if the underlying health emergency no longer exists or warrants such authorization.

In the United States, the Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. On March 17, 2020, the Secretary of HHS issued a declaration under the PREP Act and has issued subsequent amendments thereto to provide liability immunity for activities related to certain countermeasures against COVID-19. While we believe our products sold to the U.S. Government would be covered under the provisions of the PREP Act, this cannot be assured.

Pediatric information

Under the Pediatric Research Equity Act of 2003, all marketing applications for new active ingredients, indications, dosage forms, dosing regimens or routes of administration must contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred or inapplicable.

Under the Best Pharmaceuticals for Children Act, a product may be eligible for pediatric exclusivity, which adds six months to existing exclusivity periods and patent terms. This exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study.

Post-approval requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or NDA or BLA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (REMS) to assure that the benefits of the product outweigh the risks. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Product approvals may be withdrawn for non-compliance with regulatory standards, or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. Entities involved in the manufacture and distribution of approved drugs or biologics and their third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Such entities are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections for compliance with cGMP requirements and other laws. The discovery of violations could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA or NDA, including recall.

U.S. patent term restoration and regulatory data exclusivity

In certain circumstances, some U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND and the submission date of a BLA or NDA, plus the time between the submission date of a BLA or NDA and the approval of that application. Only one patent applicable to an approved product is eligible for such an extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

If the FDA approves a drug product that contains an active ingredient not previously approved, the product is typically entitled to five years of non-patent regulatory data exclusivity. Other products may be entitled to three years of regulatory data exclusivity if approval was based on the FDA's reliance on new clinical studies essential to approval submitted by the NDA applicant. If the NDA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days each existing exclusivity (patent and regulatory) related to the product.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act). Biosimilarity requires a showing that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A reference biological product is granted 12 years of regulatory data exclusivity from the time of first licensure of the product

and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

Drug development in the European Economic Area (EEA)

Medicinal products can be marketed in the EEA, which is comprised of the 27 Member States of the EU and Norway, Iceland and Liechtenstein, only if a marketing authorization from the competent regulatory agency has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Effective since January 2022, the Clinical Trials Regulation (No. 536/2014) aims to streamline and harmonize the procedures for assessment and governance of clinical trials throughout the EU and to require that information on the authorization, conduct and results of each clinical trial conducted in the EU be publicly available.

Pediatric investigation plan

An application for marketing authorization of a medicinal product for human use that is not yet authorized in the EU must include a Pediatric Investigational Plan (PIP) pursuant to the regulation on medicinal products for pediatric use (known as the Paediatric Regulation), unless a waiver applies. A scientific committee established at the European Medicines Agency (EMA), the Paediatric Committee (PDCO) assesses the content of any PIP, waivers, and deferrals for a medicinal product submitted to it and formulates an opinion thereon.

Review and approval process

In the EEA, in order to obtain a marketing authorization from the applicable regulatory authority, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes, advanced therapy medicinal products (ATMPs), orphan medicinal products, or those medicines containing a new active substance and intended to treat specific diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases), and optional for those medicines that are highly innovative or contain a new active substance, provides for the grant of a single marketing authorization that is valid throughout the EEA. In addition to the centralized procedure, a marketing authorization can also be obtained in the EEA through a national procedure, which requires a separate application to and approval determination by each country; a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision.

A conditional marketing authorization may be granted in the EU when comprehensive clinical data for the safety and efficacy of the medicinal product have not been supplied but all the following requirements are met: (i) the risk-benefit balance of the medicine is positive; (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data post-authorization; (iii) the medicine fulfills an unmet medical need; and (iv) the benefit to public health of the immediate availability on the market of the medicine outweighs the risk that additional data is still required. Conditional marketing authorizations are valid for one year, on a renewable basis. The marketing authorization holder will be required to fulfil specific obligations within certain timeframes, which may include completing ongoing trials or conducting new trials to confirm that the benefit-risk balance is positive. Once such obligations are fulfilled, provided the benefit-risk balance is still positive, a conditional marketing authorization can be converted into a standard marketing authorization.

European regulatory data protection

In the EU, new innovative products authorized for marketing (i.e., reference products) qualify for regulatory data protection consisting of eight years of data exclusivity and an additional two years of market protection upon the grant of a marketing authorization. Data exclusivity prevents generic or biosimilar applicants from referencing the innovator's data when applying for a generic or biosimilar marketing authorization. During the additional two-year period of market protection, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market protection period. There is no guarantee that a product will be considered by the EU's regulatory authorities to be an innovative medicinal product, and products may not qualify for regulatory data protection.

European orphan designation and exclusivity

Orphan drug designation is available in the EU to promote the development of products that are intended for the diagnosis, prevention, or treatment of life threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU community, or where it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development, and in each case for which no satisfactory method of diagnosis, prevention, or treatment has been

authorized (or, if a method exists, the product would be a significant benefit to those affected). Medicinal products that receive and maintain orphan drug designation following approval are entitled to 10 years of market exclusivity, which protects against applications for and the grant of marketing authorizations for similar medicinal products in the same therapeutic indication. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met. During the period of market exclusivity, marketing authorization may only be granted to a similar medicinal product for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product

The aforementioned EU rules are generally applicable in the EEA.

European data protection regulations

The EU General Data Protection Regulation (GDPR) governs the collection and use of personal data in the EU. The GDPR imposes strict requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20.0 million or 4% of the annual global revenues of the infringer, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with competent national data protection authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Non-compliance could also result in the imposition of orders to stop data processing activities.

The UK has incorporated the GDPR into UK law (the UK GDPR).The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Marketing of medicines in the EU

Similar to the Anti-Kickback Statute prohibition in the United States discussed below, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. Infringement of relevant EU laws could result in substantial fines and imprisonment. Payments may be made to physicians in limited circumstances, and in certain EU Member States such payments must be publicly disclosed. Moreover, agreements with physicians for the provision of services often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Rest of the world regulation

Outside of the United States and the EU, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. If we fail to comply with such requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, or criminal prosecution.

Coverage and reimbursement

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Additionally, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

For further information on certain risks associated with the pricing and reimbursement of our products see “Risk Factors—Sales of pharmaceutical products depend on the availability and extent of reimbursement from third-party payors, and we may be adversely impacted by changes to such reimbursement policies or rules.”

Other healthcare laws

Healthcare providers, physicians, and third-party payors, including governmental payors, such as Medicare and Medicaid in the United States, will play a primary role in the recommendation and prescription of any marketed products. Any arrangements with these parties implicate certain fraud and abuse and other healthcare laws and regulations. In the United States, these laws include, among others:

- The Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, receive, offer, or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug or any other good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.
- The federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government.
- Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing, or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information.

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act (ACA), which requires certain pharmaceutical manufacturers with products reimbursed under certain government programs to disclose annually to the federal government (for re-disclosure to the public) certain payments and other transfers of value provided to physicians, teaching hospitals and certain other licensed health care practitioners.
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor.

Additionally, certain state and foreign laws also govern the privacy and security of health information. Such data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Protection Act (CCPA) established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Further, the California Privacy Rights Act (CPRA), which took effect on January 1, 2023, has established additional obligations with respect to processing and storing personal information. The CPRA significantly modified the CCPA, including by expanding customers' rights with respect to certain sensitive personal information. While clinical trial data and information governed by HIPAA are currently exempt from the current versions of the CCPA and CPRA, other personal information is applicable due to the CPRA’s broader scope. Similar laws have been passed or proposed in numerous other states.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform.

Current and future healthcare reform legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities and affect our ability to profitably sell any approved products. The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and, annual fees based on pharmaceutical companies’ share of sales to federal health care programs. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price for any approved products.

In the United States, it is unclear whether the ACA will be overturned or further amended. We cannot predict what effect further changes to the ACA would have on our business. Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted, including the Budget Control Act of 2011, which includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers, which began in April 2013 and will remain in effect through 2031 unless additional Congressional action is taken. In 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning in 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls and price transparency,

restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs.

Environment

We are subject to state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment, breach of our regulatory obligations or expose individuals to harm, we could be liable for damages and governmental fines. Equivalent laws have been adopted in foreign countries that impose similar obligations.

CORPORATE INFORMATION

We were incorporated under the laws of the State of Delaware on July 22, 2016. We are the successor in interest to Moderna LLC, a limited liability company formed under the laws of the State of Delaware in 2013. Moderna LLC was the successor in interest to Moderna Therapeutics, Inc., a Delaware corporation incorporated in 2009 as Newco LS18, Inc. by Flagship Pioneering. In August 2018, we changed our name from Moderna Therapeutics, Inc. to Moderna, Inc. Our principal corporate office is located at 200 Technology Square, Cambridge, MA 02139, and our telephone number is (617) 714-6500.

Our website, www.modernatx.com, including the Investor Relations section, www.investors.modernatx.com; corporate blog www.modernatx.com/moderna-blog, and our Statements and Perspectives webpage, https://investors.modernatx.com/Statements--Perspectives/default.aspx; as well as our social media channels: Facebook, www.facebook.com/modernatx; X, www.twitter.com/moderna_tx; and LinkedIn, www.linkedin.com/company/modernatx; contain a significant amount of information about us, including financial and other information for investors. We encourage investors to visit these websites and social media channels as information is frequently updated and new information is shared. The information on our website and that we disclose through social media channels is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the Securities and Exchange Commission (the SEC).

We make available free of charge on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports.

The SEC also maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC.

Item 1A. Risk Factors

You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations and the market price of our common stock.

Risks related to commercialization and our products

Evolving dynamics in the market for COVID-19 vaccines are likely to impact our financial results, which are likely to result in lower product revenues in 2024 than we have experienced in recent years.

Through 2023, our only approved product and sole source of product sales has been our COVID-19 vaccine. The global market is transitioning to an endemic, commercial market for COVID-19 vaccine sales, resulting in different market and production dynamics than during the pandemic, including a more fragmented customer base, less predictability in orders, greater seasonality of demand, increased distribution costs, and higher costs of goods sold. Furthermore, our assumptions regarding the product presentation that will be accepted or preferred by the market (e.g., single-dose presentation), which could vary by market, may prove incorrect. In addition, certain U.S. private vaccine market practices, including regarding discounts, rebates and returns, may cause us to realize significantly lower revenues than list prices. We may also be adversely affected by similar market practices outside of the United States.

We recognized $6.7 billion of sales for COVID-19 vaccines delivered in 2023, compared to $18.4 billion in 2022 and $17.7 billion in 2021, as demand for COVID-19 vaccines declined. We anticipate that sales of COVID-19 vaccines are likely to be lower in 2024 than 2023. We expect the market for COVID-19 vaccines to evolve based on a number of factors, including medical need, viral evolution, public health authority recommendations and consumer motivation to vaccinate. In the third quarter of 2023, we significantly resized our manufacturing infrastructure as we shifted to an endemic COVID-19 vaccine market, and we may in the future incur additional costs associated with exiting commitments with suppliers for raw materials and contract manufacturing organization (CMOs). As a result of lower demand, we have experienced, and may in the future experience, increased costs with respect to raw material suppliers as we seek to exit or modify our purchase commitments. Further, we have entered, and may in the future enter, into non-cancellable or take-or-pay purchase commitments for raw materials that require a long lead time to procure, increasing our commitment exposure. If we cannot effectively manage evolving demand dynamics, our business, financial condition, results of operations and prospects may suffer.

Additionally, we may not see demand materialize for our products consistent with our projections. This may lead to lower than expected commercial sales or requests to defer, renegotiate or cancel existing contracts. Further, we may find that we need to dedicate greater resources to our commercial efforts than anticipated, and we may not realize a return on this investment.

We may encounter difficulties producing or shipping our products consistent with our projections or future contractual commitments.

We may encounter difficulties producing or shipping our products, including our COVID-19 vaccine or other future products, consistent with our current expectations or on the terms set forth in our supply agreements or future sales contracts. Our ability to commercialize our products depends on our manufacturing capability, both at our own facilities and those of our partners, particularly for fill-finish capabilities. Further, adapting our COVID-19 vaccine to new variants requires significant coordination with our partners, including for the sourcing of raw materials and production. Any capacity or production issues or delays experienced by our partners may cause us to fail to meet obligations under our supply agreements.

We have limited sales, distribution and marketing experience and may be unable to effectively establish such capabilities or supplement our capabilities by entering into agreements with third parties.

We have limited experience as a commercial organization and face risks and uncertainties as we shift to an endemic COVID-19 vaccine market and prepare for the commercial launch of other medicines, including our anticipated RSV vaccine launch in 2024. As a result of this limited commercial experience, we may be unsuccessful in accurately anticipating future rates of return for our products, which may adversely impact our accounting estimates. Additionally, we may seek to enter into agreements with others to utilize their marketing and distribution capabilities, but may be unable to enter into agreements on favorable terms, if at all. If we rely on others to commercialize our products, our revenues may be lower than if we commercialized these products ourselves. In addition, we may have little or no control over such third parties' sales efforts. If our partners commit insufficient resources to commercialize our products, and we cannot independently develop necessary marketing capabilities, we may be unable to generate sufficient product revenue to sustain our business.

The pharmaceutical market is intensely competitive, and we may not compete effectively in the market for existing products, new treatment methods and new technologies.

The pharmaceutical market is intensely competitive and evolving. Many companies, academic institutions, governmental agencies and public and private research organizations are developing products for the same diseases that we are targeting or expect to target and such other parties may have:

- greater resources and experience than us at every stage of drug discovery, development, testing, approval, manufacturing and commercialization;
- multiple products that have been approved or are in late stages of development; and
- arrangements in our target markets with purchasers, governments, leading companies and research institutions.

We face intense competition with respect to our COVID-19 vaccine, and it may not continue to compete favorably with existing or future vaccines and treatments. Other vaccines or treatments could prove to be safer, more effective, more convenient, have fewer side effects, be easier to ship or distribute or able to be developed at a lower cost than our vaccine. Even if our products demonstrate superiority to those of competitors, consumers and the public may fail to appreciate that benefit, or existing purchase commitments for a competitor's product may discourage them from purchasing from us. These factors, or the perception of these factors, could lead to a competitor's vaccine or treatment being more successfully commercialized. Further, the mRNA medicines field is growing rapidly, with increased competitive pressure from large and more established pharmaceutical companies. The actual or perceived success or failure of others may adversely impact our ability to commercialize our products.

We also will face competition from products that have already been approved and accepted by the medical community to treat certain conditions we target. For example, we are developing a seasonal flu vaccine, for which there is a well-developed market, and we may be unsuccessful in developing a product or achieving market share. Our RSV vaccine, which we expect to launch beginning in 2024, will also face competition from existing RSV vaccines. In markets that we enter after competitors have already introduced a competing product, we may have difficulty achieving market share. Further, we may need to offer more favorable terms to gain market share in an existing market or to compete in a new market, which may negatively impact our profitability.

If we successfully develop and obtain approval for other product candidates, we may compete with products under development by competitors based on many factors, including the relative safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Our competitors may be more successful in commercializing their products, which would adversely affect our business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We may be unsuccessful or delayed in updating our COVID-19 vaccine to protect against future variants of the SARS-CoV-2 virus, and updated versions of our COVID-19 vaccine may not protect against such variants.

As the SARS-CoV-2 virus continues to evolve, new strains of the virus may prove more transmissible or cause more severe forms of COVID-19 than earlier strains. Our current COVID-19 vaccines could be ineffective, or less effective than desired, in protecting against these new variants. Additionally, our decisions regarding vaccine development will be informed by guidance from the FDA and foreign regulatory authorities, which may impact the timing of development for our COVID-19 vaccines.

We may experience delays in producing variant-specific vaccines. Further, different regulators may issue differing guidance regarding vaccine composition or populations who should receive a vaccine. If our efforts to develop variant-specific vaccines against future variants are unsuccessful, we are slower than competitors to develop such vaccines or our vaccines prove less effective than competitors' vaccines, we could suffer reputational harm, loss of market share and adverse financial results. Additionally, we may expend significant resources adapting our vaccines or conducting clinical trials to protect against variants, but a market for our adapted vaccines may fail to develop or demand may not align with our projections or cost expenditures.

The commercial success of our products will depend on the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

The commercial success of our products will depend in part on the medical community, patients and third-party or governmental payors accepting mRNA medicines, and our products in particular, as medically useful, cost-effective and safe. The degree of market acceptance of our products will depend on numerous factors, including:

- the potential efficacy and advantages over alternative treatments;

- the ability to offer products at competitive prices;
- the duration of protection provided by our products compared to those of competitors;
- acceptance of mRNA products generally and the availability of competing non-mRNA medicines that may be preferred by the medical community or the public;
- the prevalence and severity of any side effects, including any limitations, restrictions (including for use together with other medicines) or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other products or therapies with which our products are co-administered;
- relative convenience and ease of administration;
- the willingness of the target patient population to try, and physicians to prescribe, new therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- whether our product presentation meets customer demand (e.g., for single-dose presentations, or combination vaccines);
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance will be unknown until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources, especially due to the complexity of our programs, and may never be successful.

Sales of pharmaceutical products depend on the availability and extent of reimbursement from third-party payors, and we may be adversely impacted by changes to such reimbursement policies or rules.

Sales of pharmaceutical products in general depends to a significant extent on adequate coverage, pricing and reimbursement from third-party payors. When a new product is approved, the availability and extent of government and private reimbursement, and the pricing, for that product may be uncertain. For example, it is uncertain whether any combination respiratory vaccine we develop, if approved, would qualify for coverage under Medicare Part B. Additionally, pricing and reimbursement for any product we develop may be adversely affected by a number of factors, including:

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs; and
- consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value.

Our ability to set the price for any product we develop will vary significantly by country. Our inability to obtain and maintain adequate prices in a particular country may limit the revenues from our products within that country and adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. This may create the opportunity for third-party cross-border trade or influence our decision whether to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products, particularly our therapeutic products or those that are individualized for a particular patient. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is a covered benefit under its health plan, safe, effective and medically necessary, appropriate for the specific patient, cost-effective and neither experimental nor investigational.

Additionally, target patient populations for some of our product candidates may be small (e.g., for rare genetic diseases) or require individual customization (e.g., for our INTs). The pricing and reimbursement of our medicines, if approved, must be adequate to support commercial infrastructure. If we cannot obtain adequate levels of reimbursement, we may be unable to successfully market and sell our products. The manner and level at which reimbursement is provided for services related to our products (e.g., for administration to patients) is also important. Inadequate reimbursement for such services may discourage physicians from prescribing or recommending our products, adversely affecting our ability to market or sell those products.

The market opportunities for our products and product candidates may be smaller than we believe, or we may be unable to successfully identify clinical trial participants.

We focus certain of our research and product development activities on treatments for severe rare genetic diseases, where the patient populations are difficult to ascertain or small. Additionally, we expect to initially seek approval of our INT and intratumoral immuno-oncology product candidates for use by patients with relapsed or refractory advanced disease, i.e., the populations the FDA often approves new therapies for initially. If any such medicines prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy. There is no guarantee that our products, if approved, would be approved for earlier lines of therapy and, prior to any such approvals, we may have to conduct additional clinical trials.

Our estimates of addressable patient populations are based on our beliefs, and have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may be lower than expected and potential clinical trial participants or patients may not be otherwise amenable to treatment with our product candidates or products, or new clinical trial participants or patients may become increasingly difficult to identify or gain access to. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, these medicines may never be profitable.

Risks related to our pipeline, product development and regulatory review

Preclinical development is lengthy and uncertain, especially for mRNA medicines, and our preclinical programs or product candidates may be delayed or terminated.

Much of our pipeline is in preclinical development, and these programs could be delayed or not advanced into the clinic. Before we can initiate clinical trials for a product candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practice (GLP) toxicology testing. We must also complete extensive work on Chemistry, Manufacturing, and Controls (CMC) activities to be included in an IND submission. CMC activities for mRNA medicines require extensive manufacturing processes and analytical development, which is uncertain and lengthy. We have had and may in the future have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our product candidates. If we must produce new batches, our preclinical studies could be delayed. We cannot be certain of the timely completion of our preclinical testing and studies, whether the FDA or other regulators will accept the results or if the outcome of our preclinical testing, studies and CMC activities will ultimately support further development of our programs. As a result, we may be unable to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and such applications may not result in the FDA or other regulators allowing clinical trials to begin.

Clinical development is lengthy and uncertain, and our clinical programs may be delayed or terminated, or may be more costly to conduct than we anticipate.

Clinical testing is expensive, complex and lengthy, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved as products. We may be unable to initiate, may experience delays in or may have to discontinue clinical trials for our product candidates. We and our strategic collaborators also may experience unforeseen events during, or as a result of, any clinical trials that we or they conduct that could delay or prevent us or them from successfully developing our product candidates and gaining approval from regulators. Events that might prevent us from proceeding with clinical trials could include:

- regulators, Institutional Review Boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective contract research organizations (CROs);
- changes to the scale or site of our manufacturing could cause significant delays or changes in our clinical trial designs;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish or achieve clinically meaningful endpoints for our studies;
- if we make changes to our product candidates after clinical trials have commenced (which we have done in the past), we may be required to repeat earlier stages or delay later stages of clinical testing;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;

- our product candidates, or other medicines in the same class as ours, may have undesirable side effects, such as the immunogenicity of the LNPs or their components, the immunogenicity of the protein made by the mRNA or degradation products, any of which could lead to serious adverse events, or other effects;
- administration of our LNPs could lead to systemic side effects related to the components of the LNPs and could contribute to immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions or reactions to PEG-lipids;
- significant adverse events or other side effects could be observed in our clinical trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the applicable clinical trial protocol or withdraw from the applicable clinical trial, which may require that we add new clinical trial sites;
- regulators may impose a complete or partial clinical hold on a clinical trial, or we or our investigators, IRBs or ethics committees may suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to an unacceptable benefit-risk ratio;
- regulators may impose a complete or partial clinical hold on clinical trials of other companies working on mRNA medicines;
- the cost of preclinical or nonclinical testing and studies and clinical trials of product candidates may be greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety and efficacy concerns regarding our product candidates will be considered by us and by the FDA and other regulators as we pursue clinical trials of new product candidates, develop effective informed consent documentation and work with IRBs and scientific review committees (SRCs);
- safety or efficacy concerns could arise from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours;
- adverse side effects could be observed in future clinical trials where our product candidates are administered in combination with other therapies (such as the co-administration of our INT product candidate, mRNA-4157); and
- a lack of adequate funding to continue a particular clinical trial.

Before commencing later-stage clinical trials for our programs, we must develop assays to measure and predict the potency of a given dose of our product candidates. Any delay in developing assays that are acceptable to the FDA or other regulators could delay the start of future clinical trials.

Additionally, we have conducted and may conduct in the future "open-label" clinical trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate, an approved drug or a placebo. The results from an open-label clinical trial may not be predictive of future clinical trial results from a controlled environment with a placebo or active control. Further, the FDA or other regulators may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Significant preclinical or nonclinical testing and studies or clinical trial delays for our product candidates could allow our competitors to bring products to market before we do and could harm our business, financial condition and prospects significantly.

There are risks that are unique to each of our programs and modalities and risks that are applicable across programs and modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval or commercialize our products, or cause us to experience significant delays in doing so.

Certain features in our product candidates, including those related to mRNA, chemical modifications, surface chemistries, LNPs and their components, may result in risks that apply to some or all of our programs and modalities. As our product candidates progress, we or others may determine that certain of our risk allocation decisions were incorrect or insufficient, we made platform-level technology mistakes, individual programs or our mRNA science in general has technology or biology risks that were unknown or under-appreciated, our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our product candidates for clinical trials or otherwise impair our manufacturing or we have allocated resources in such a way that we cannot recover large investments or rapidly re-direct capital.

We utilize earlier programs in a modality to understand the technology risks within the modality, including the program's manufacturing and pharmaceutical properties. Even if our earlier programs in a modality are successful in any phase of development, any program may fail at a later phase of development, and other programs within the same modality may fail at any phase of development, including at phases where earlier programs in that modality were successful. This may be a result of technical challenges or biology risk unique to that program. The biology risk across the majority of our pipeline represents targets and pathways not clinically validated by one or more approved drugs, and the risk that the targets or pathways that we have selected may not be effective will continue to apply across the majority of our current and future programs.

As we progress our programs through clinical development, new technical challenges may arise that cause an entire modality to fail. Additionally, any portfolio-spanning risks, whether known or unknown, such as an increased risk of a particular type of side effect, if realized in any one of our programs, would have a material and adverse effect on our other programs and on our business as a whole.

There are also specific additional risks to certain of our modalities and programs. For example, prophylactic vaccines typically require clinical testing in up to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Even if we observe positive safety, tolerability and levels of immunogenicity in early clinical trials, we may not observe acceptable safety or efficacy profiles in later-stage trials required for approval of these programs.

There are many clinical and manufacturing challenges specific to our INT product candidates and any other neoantigen cancer vaccines we may develop. These risks include a rapid production turn-around time measured in weeks in order to supply patients in our clinical trials before further progression and mutation of their tumors, the significant costs incurred in making individualized medicines and potential lack of immune responses due to the biology of the tumor or immune status of the patient. These risks apply to our INT product candidates and other neoepitope investigational medicine programs.

Additionally, there may be challenges in delivering an adequate quantity of active pharmaceutical ingredient (API) required to drive efficacy due to the limitation in volume of API that can be delivered to a specific location, like a tumor or injured tissue. Our investigational therapies for local injections often require specialized skills for conducting a clinical trial that could delay clinical trials or slow or impair commercialization of a product due to the poor adoption of injected local therapeutics or intratumoral therapies. In addition, the uncertain translatability of target selection from preclinical animal models, including mouse and non-human primate models, to successful clinical trial results may be impossible, particularly for immuno-oncology and systemic therapies, and cancer vaccines. In general, several biological steps are required for delivery of mRNA to translate into therapeutically active medicines. These processing steps may differ between individuals or tissues, potentially leading to variable levels of therapeutic protein, variable activity, immunogenicity or variable distribution to tissues for a therapeutic effect. Gene therapies and mRNA medicines may activate one or more immune responses against any and all components of the drug product (e.g., the mRNA or the delivery vehicle, such as an LNP) as well as against the encoded protein, giving rise to potential immune reaction related adverse events. Eliciting an immune response against the encoded protein may impede our ability to achieve a pharmacologic effect upon repeat administration or a side effect. These risks apply to all of our programs, including our systemic secreted therapeutics and systemic intracellular therapeutics modalities.

We may experience delays in enrolling participants in our clinical trials.

Enrolling participants in our clinical trials is critical to our success. Difficulties or delays in enrolling a sufficient number of clinical trial participants, or those with required or desired characteristics, may result in increased costs or affect the timing or outcome of our planned clinical trials, which could prevent trial completion and adversely affect our ability to advance the development of and obtain regulatory approval for our product candidates. We may slow enrollment in a trial to focus on achieving greater diversity in the subject population, as we did in the Phase 3 clinical trial of our original COVID-19 vaccine.

Participant enrollment is affected by many factors, including:

- severity of the disease under investigation;
- complexity and design of the clinical trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question, including age-based eligibility criteria limiting subject enrollment to adolescent or pediatric populations;
- proximity and availability of clinical trial sites for prospective trial participants;
- availability of competing therapies and clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit qualified clinical trial investigators;
- clinicians' and trial participants' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- adverse results or other adverse safety signals in our trials or related to other product candidates, and the resulting negative publicity, could discourage potential clinical trial participants and their doctors from participating in our trials; and
- our ability to obtain and maintain participant informed consent.

Additionally, we may have limited or no ability to influence enrollment in clinical trials where we have entered into strategic alliances pursuant to which our collaborators control clinical development. Even if we or our strategic collaborators can enroll clinical trial participants, there is no guarantee that such participants will ultimately be dosed as part of, or complete, a clinical trial.

mRNA drug development has substantial clinical development and regulatory risks due to the novel nature of this new class of medicines, and the negative perception of the efficacy, safety or tolerability profile of any product candidates that we or others develop could adversely affect our ability to conduct our business, advance our product candidates or obtain regulatory approvals.

Very few mRNA medicines have been authorized or approved to date by the FDA or other regulators, and efficacy, safety and immunogenicity data and real-world evidence with respect to mRNA medicines continue to accumulate. We may observe new, more frequent or more severe adverse events in subjects participating in ongoing clinical trials or among individuals vaccinated with our COVID-19 vaccine. For example, some studies have suggested that our COVID-19 vaccine may be associated with higher rates of myocarditis and pericarditis in young males compared to other COVID-19 vaccines. If similar observations are made in recipients of our other products or product candidates, or if other unexpected safety issues arise, we could suffer significant damage to our reputation and that of our mRNA platform. Such events could lead to other issues, including delays in our other programs, the need to re-design our clinical trials and the need for significant additional financial resources. In addition, the FDA and other regulators may interpret data from our clinical trials differently than we do and such agencies may require us to conduct additional studies or analyses, which could delay or prevent us from obtaining full regulatory approvals in certain jurisdictions or for certain demographics. For example, in October 2021, the FDA requested that we explore a lower dosage for our COVID-19 vaccine in adolescents, which extended the length of clinical trials in this population prior to receiving regulatory authorization.

Successful discovery and development of mRNA medicines by us or our strategic collaborators is highly uncertain and depends on many factors beyond our or their control. We constantly make business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology and manufacturing processes, which ultimately may be unsuccessful.

Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds or fail to reach the market for many reasons, including:

- nonclinical or preclinical study, or clinical trial, results may show potential mRNA medicines to be less effective than desired or to have harmful or problematic side effects or toxicities;
- adverse results in our clinical trials, or in those of others developing similar products, or adverse effects relating to mRNA, or our LNPs, may lead to negative publicity or delays in or termination of our programs;
- the efficacy or safety of a combination vaccine product candidate could be less than that seen with the administration of the vaccines separately, which could prevent the combination product from obtaining regulatory approval;
- adverse events related to products that are perceived to be similar to mRNA medicines, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our product candidates and less demand for any product that we may develop;
- the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our product candidates may have a dependent or independent effect on safety, tolerability and efficacy, which may be species-dependent;
- manufacturing failures or insufficient supply of cGMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make mRNA medicines commercially unattractive;
- changes that we make to optimize our manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability and efficacy profile of our product candidates;
- pricing or reimbursement issues or other factors that delay clinical trials or make any mRNA medicine uneconomical or noncompetitive with other therapies;
- our large pipeline of product candidates could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole;
- failure to timely advance our programs or a failure or delay in receiving necessary regulatory approvals due to, among other factors, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, preparation of a BLA, or the equivalent application, discussions with the FDA or EMA, a regulatory request for additional nonclinical or clinical data or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding;
- new legislation or regulations passed by U.S., state or foreign governments in response to negative public perception of mRNA medicines; and

- the proprietary rights of others and their competing products and technologies that may prevent our mRNA medicines from being commercialized.

Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There are no pharmacologic therapies approved to treat the underlying causes of many diseases that we are currently attempting to address or may address in the future. For instance, for many of the rare diseases for which we are developing treatments, few clinical trials have been attempted, and there are no approved drugs to treat these diseases. As a result, the design and conduct of clinical trials of product candidates for the treatment of these disorders and other disorders may take longer, be more costly or be less effective due to the novelty of development in these diseases.

Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our strategic collaborators conduct. Further, even if we achieve the pre-specified criteria, our clinical trials may produce unpredictable or inconsistent results compared against the more traditional efficacy endpoints in the trial. The FDA could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and may view the efficacy results in the context of safety as not being supportive of licensure. Regulators in other countries may make similar findings with respect to these endpoints.

Certain mRNA therapies are classified as gene therapies by the FDA and the EMA. The association of our medicines with gene therapies could result in increased regulatory burdens, impair the reputation of our investigational medicines or negatively impact our platform or our business.

There are only a few approved gene therapy products in the United States or foreign jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Regulatory requirements governing gene therapy products have evolved and may continue to change in the future, and the implications for mRNA therapies are unknown. For example, the FDA has established an office, now called the Office of Therapeutics Products (OTP), within its Center for Biologics Evaluation and Research (CBER) to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the EU, certain mRNA therapies have been characterized as gene therapy medicinal products, which falls within a broader category known as Advanced Therapy Medicinal Products (ATMPs), which are subject to additional regulatory requirements. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us; for example, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification of mRNA therapies. Notwithstanding the differences between mRNA medicines and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the EU and potentially other countries could adversely impact our ability to develop our product candidates. For instance, a clinical hold on gene therapy products may apply to our mRNA product candidates irrespective of the differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapies caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our clinical trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory agencies may negatively affect our business by lengthening the regulatory review process, requiring us to perform additional or larger studies or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates, or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates.

Our work in genomic editing is subject to all risks associated with gene therapies. Although there have been significant advances in recent years in fields of gene therapy and genome editing, *in vivo* CRISPR-based genome editing technologies are relatively new and their therapeutic utility is largely unproven. Public perception and related media coverage of potential therapy-related efficacy or safety issues, as well as ethical concerns related specifically to genome editing, may adversely influence the willingness of subjects to participate in clinical trials. In addition, any review conducted by an institutional biosafety committee may result in delay or prevent initiation of a gene therapy clinical trial.

Additionally, if any such therapeutic is approved, physicians and patients may be slow or fail to accept these novel and personalized treatments. Physicians, health care providers and third-party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training and may choose not to administer the therapy. Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies. In addition, responses by federal and state agencies, congressional committees and foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations or medical standards that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs.

If we cannot obtain, or are delayed in obtaining, required regulatory approvals, we will be unable to commercialize, or will be delayed in commercializing, product candidates we may develop.

Any mRNA medicine we may develop and the activities associated with its development and commercialization are subject to comprehensive regulation by the FDA and comparable foreign regulators. To obtain required regulatory approvals to commercialize any product candidate, we and our strategic collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a marketing authorization application (MAA) to the EMA, and similar marketing applications to comparable foreign regulators, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product.

To date, we have only received regulatory authorizations for our COVID-19 vaccine, and our current or future product candidates may never obtain regulatory approval. We have limited experience in filing and supporting the necessary applications for marketing approvals and may need to rely on third parties to assist us in this process. Although we expect to submit BLAs for our mRNA product candidates in the United States, other jurisdictions may consider our mRNA product candidates to be new drugs, not biologics, and require different marketing approval applications. Preclinical studies and clinical trials conducted in one country may not be accepted by regulatory authorities elsewhere, and approval in one country does not guarantee regulatory approval in another.

Additionally, the process of obtaining marketing approvals, both in the United States and abroad, is expensive, time-consuming and uncertain, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in law or changes in regulatory review may delay the review of a submitted product application. The FDA and comparable foreign regulators have substantial discretion in the approval process and may refuse to accept any marketing approval application or may decide that our data are insufficient for marketing approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Additional delays or non-approval may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval.

The FDA and other foreign regulators review the CMC section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies conduct pre-approval inspections at the time of a BLA. Any negative findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the product candidate.

If we experience delays in obtaining, or fail to obtain, regulatory approval of any product candidate we develop, the commercial prospects for such product candidate would be harmed, and our ability to generate revenues will be materially impaired.

Emergency authorizations that we have received for our COVID-19 vaccine for certain demographics, including pediatrics, are temporary and could be revoked.

We currently operate under an EUA provided by the FDA for our COVID-19 vaccines that are administered as a primary series in pediatric populations. The FDA may revoke this authorization for a variety of reasons, including if it determines that the underlying health emergency no longer exists or warrants such authorization. If new data emerges that shows the benefits of our vaccine do not continue to outweigh its risks, emergency authorizations that we have received for our COVID-19 vaccines from the FDA or other regulators could be revoked if the conditions for granting such authorizations no longer apply. If such authorizations were revoked, without receiving final approval to distribute our COVID-19 vaccines, our business would be adversely impacted.

Our products are, and any future products will be, subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, we may remain subject to significant restrictions on the indicated uses or marketing of our product and ongoing requirements for potentially costly post-approval studies-such as those required under an accelerated approval by the FDA or other similar type of approval-or post-market surveillance. For example, the holder of an approved BLA must monitor and report adverse events and monitor and report any failure of a product to meet the specifications in the BLA, as well as submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Additionally, pharmacovigilance obligations under the regulatory regimes of the jurisdictions where our products are distributed require us to collect, process, analyze and monitor safety data and to identify and evaluate adverse reactions to our products as they are administered in those jurisdictions. If we or any of our partners assisting us in meeting these obligations cannot comply with relevant regulations, we may be subject to sanctions, increased costs and reputational harm, or our regulatory authorizations to distribute our vaccines in the relevant jurisdiction may be revoked or curtailed.

Furthermore, advertising and promotional materials must comply with FDA rules and regulations and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

We are required by the FDA to conduct post-marketing studies for our COVID-19 vaccine (mRNA-1273) to further assess the risks of myocarditis and pericarditis following vaccination. Additionally, we have committed to conducting additional post-marketing safety studies, including conducting a study to evaluate pregnancy and infant outcomes after receipt of mRNA-1273 during pregnancy. We or others could identify previously unknown side effects, or known side effects could be observed as being more frequent or severe than in clinical trials or earlier post-marketing periods. If we, our contract manufacturers or other strategic collaborators fail to comply with applicable post-approval regulatory requirements, a regulatory agency may issue a warning letter asserting that we are in violation of the law, seek an injunction or impose civil or criminal penalties or monetary fines, suspend or withdraw regulatory approval or revoke a license, suspend any ongoing clinical trials, refuse to approve a pending BLA or supplements to a BLA submitted by us, seize or recall products or product candidates, or require field alerts to physicians, pharmacists and hospitals or refuse to allow us to enter into supply contracts. We could also be required to conduct additional nonclinical studies or clinical trials, or implement changes in labeling or to our manufacturing processes, specifications or facilities. Initiation of any government investigation or lawsuit, including class-action lawsuits, would require us to expend significant time and resources in response and would likely generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our COVID-19 vaccine, or any future approved products, and generate revenues.

Additionally, the FDA or other foreign regulators could require us to adopt Risk Evaluation and Mitigation Strategies (REMS) for any product to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including the suspension or withdrawal of approvals and licenses, the addition of warning labels, changes to the way a product is administered, the requirement to conduct further clinical trials, lawsuits or increased liability for harm to patients and their children and reputational harm to us. Any of these events could prevent us from achieving or maintaining market acceptance of any products we develop and could have a material adverse impact on our business, financial condition, results of operations and prospects.

Risks related to the manufacturing of our commercial products and product candidates

Our mRNA products and product candidates are based on novel technologies and are complex and difficult to manufacture. We or our third-party manufacturers may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping for any of our products.

The manufacturing processes for our mRNA medicines are novel and complex. We and our collaborators have experienced and may continue to encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping, including delays as our supply chain expands and grows more complex. We could experience issues resulting from complexities of producing batches at larger scale, equipment failure, human error, choice and quality of raw materials and excipients, analytical testing technology and product instability. Further, mRNA medicines encapsulated in LNPs must be developed and manufactured under well-controlled conditions, or pharmacological activity can be adversely impacted.

In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has in the past and may in the future result in our having to resupply

batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our or our strategic collaborators' ability to continue clinical trials or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

Our high rate of innovation causes a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships.

In many cases, we may need to utilize multiple batches of drug substance and drug product to meet the supply requirement of a single preclinical study or clinical trial. Failure in our ability to scale up batch size or failure in any batch, which we have experienced in the past, may lead to a substantial delay in our clinical trials or in the commercialization of any approved product. For example, the changes we make as we continue developing new manufacturing processes for our drug substance and drug product may impact specification and stability of the drug product, and may lead to failure of batches, resulting in a substantial delay in delivery of commercial product or conduct of our clinical trials. Our mRNA product candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved medicine. This poses risk in supply requirements, wasted stock and higher cost of goods.

We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our medicines. If we encounter unexpected performance issues with such equipment, we could encounter delays or interruptions to clinical and commercial supply. Due to the number of different programs, we may have cross contamination of product candidates inside of our factories, CROs, suppliers or in the clinic that affect the integrity of our product candidates.

As we scale the manufacturing output for commercial production and particular programs, we plan to continuously improve yield, purity and the pharmaceutical properties of our products and product candidates from IND-enabling studies through commercial launch, including shelf-life stability, and solubility properties of drug product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after a change in process, more time will be required for pharmaceutical property testing, such as 6 or 12 month stability testing. That may require resupplying clinical material or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that have a single source of supply, are new to the pharmaceutical industry and are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our products or product candidates.

We have established several analytical assays and may have to establish several more to assess the quality of our mRNA product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA product candidates until the manufacturing or testing process is rectified.

As we grow as a commercial company and our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We rely on third-party service providers, all of whom have inherent risks in their operations.

We have limited experience at larger scale production necessary to support large-scale clinical trials and commercial sales. Completion of our trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial scale. We expect to continue to make significant investments in our manufacturing capacity and commercial network as we continue to expand our commercial launch efforts. We are building regional manufacturing capability globally and are subject to risks associated with building and operating in foreign jurisdictions.

To supplement our internal manufacturing infrastructure, we have entered into agreements for the production, as well as for commercial fill-finish manufacturing, of our products to supply markets globally. We may need to engage additional third parties in the future to meet our capacity needs. If we cannot enter into such arrangements on favorable terms, or at all, our ability to develop, manufacture and distribute our products would be adversely affected. Further, efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. If we are unable to institute

necessary controls related to product development, manufacturing and quality, we may encounter difficulties producing our products on the timelines and in the quantities set forth in our supply agreements or to meet potential future demand.

We currently utilize, and expect to continue to utilize, third parties to, among other things, manufacture raw materials, components, parts, and consumables and to perform quality testing. If the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these materials and services. Demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts and consumables required to manufacture our mRNA product candidates. The use of service providers and suppliers could expose us to risks, including:

- termination or non-renewal of supply and service agreements in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of these suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the supplier or service provider; and
- inspections of third-party facilities by regulatory authorities that could have a negative outcome and result in delays to or termination of their ability to supply our requirements.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine. Regulatory authorities may also require us to register our facilities or those of another supplier if we terminate an existing third-party manufacturer relationship, which could lead to delays or our inability to supply a particular market. A third-party manufacturer may also encounter difficulties in production, including:

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced regulations that vary in each country where products might be sold; and
- lack of capital funding.

Any delay or interruption could adversely affect our business, financial condition or results of operations.

We are subject to operational risks associated with the physical and digital infrastructure at our manufacturing facilities and those of our external service providers.

Our manufacturing facilities incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. The digitization of our facilities exposes us to the risk of process equipment malfunctions. These risks include potential system failures or shutdowns due to internal or external factors including, design issues, system compatibility or potential cybersecurity compromises, incidents or breaches. Upgrades or changes to our systems, infrastructure or the software that we implement, use, or upon which our business relies, may result in the introduction of new cybersecurity vulnerabilities and risks.

Our facilities and infrastructure or those of our contract manufacturers or other third-party providers may also be subject to attacks or acts of sabotage by outside actors, contractors or employees. Any disruption in our or our contract manufacturers' manufacturing capabilities could cause delays in production capacity for our drug substances or products or a shutdown of facilities, could impose additional costs, cause us to fail to meet certain product volume or delivery timing obligations, or may require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could adversely affect our business, financial condition, results of operations, and prospects.

As we expand our development and commercial capacities, we have and expect that we will continue to establish additional manufacturing capabilities in the United States, as well as in other countries, such as Australia, Canada and the United Kingdom. This expansion may lead to regulatory delays or prove more costly than anticipated. If we fail to select suitable locations, complete construction in an efficient manner, engage effectively with local regulators, recruit the required personnel or manage our growth effectively, the development and production of products or our product candidates could be delayed or curtailed. We will require significant additional investments in our manufacturing processes as we expand our manufacturing infrastructure.

Our products and product candidates are sensitive to shipping and storage conditions, which, in some cases, requires cold-chain logistics and subjects them to risk of loss or damage.

Our products and product candidates are sensitive to temperature, storage and handling conditions, and we could lose medicines if the product or product intermediates are not stored or handled properly. Shelf life for our products and product candidates is variable, and they may expire prior to use. Cold-chain logistics are required for certain of our products and product candidates. If we or third-party distributors do not maintain effective cold-chain supply logistics, then we may experience returned or out of date products and product may be rendered unusable. This has led and could lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or commercial sale. In addition, the cost associated with such transportation services and the limited pool of vendors could cause supply disruptions.

We are subject to significant regulatory oversight regarding manufacturing our products and product candidates. Our manufacturing facilities or those of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet current Good Manufacturing Practice (cGMP) requirements could result in significant delays in any approval of and costs of our products.

The manufacturing of medicines for clinical trials or commercial sale is subject to extensive regulation, and components of such products must be manufactured in accordance with cGMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program. The regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive. Such production process issues include:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMP and manufacturing controls. If we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections, or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may negatively impact the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for our products is subject to the FDA and foreign regulatory authority approval process. If we or our third-party manufacturers are unable to reliably produce products or product candidates to specifications acceptable to regulatory authorities, we or our strategic collaborators may not obtain or maintain the approvals needed to commercialize such products. Even if regulatory approval is obtained for any of our mRNA medicines, there is no assurance that either we or our CMOs will be able to manufacture the approved medicine to specifications acceptable to the FDA or other regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods, which, in turn, could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our contract manufacturers supply or manufacture materials or products for other companies and their failure to meet applicable regulatory requirements may affect the regulatory status of their facilities. In addition, to the extent that we rely on foreign contract manufacturers, we are subject to additional risks, including the need to comply with import and export regulations.

The FDA, the EMA and other foreign regulatory authorities may require us to submit product samples of any lot of any approved product, together with the protocols showing the results of applicable tests, at any time. In some cases, regulators may prohibit us from distributing a lot or lots until it authorizes release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may cause unacceptable changes in the product, resulting in lot failures or product recalls. Our third-party contract

manufacturers have experienced lot failures resulting in product recalls of our COVID-19 vaccine. Lot failures have caused, and lot failures or product recalls in the future with respect to product produced by either our own or our third-party manufacturers' facilities could cause, us and our strategic collaborators to delay clinical trials or product launches, which could harm our business, financial condition, results of operations and prospects.

We and our manufacturing partners also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes and operations or those of our manufacturing partners, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Additionally, we may not be able to control for or detect intentional sabotage or negligence by any employee or contractor.

Our INT product candidates are uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in production.

We custom design and manufacture INTs that are unique and tailored specifically for each patient. Manufacturing unique lots of INTs is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the patient site of care; and
- the ability to define a consistent safety profile at a given dose when each participant receives a unique therapy.

We have built and installed custom manufacturing equipment for INTs incorporated into a dedicated unit at our Norwood, Massachusetts facility. This equipment may not function as designed, resulting in deviations in the drug product produced, which could lead to increased batch failure and the inability to supply patients enrolled in a clinical trial. Additionally, as we continue our current Phase 3 INT trials, expand to additional tumor types and prepare for commercialization, we anticipate an increase in manufacturing demand for our INTs that will require ongoing investments. Some of the additional equipment that will be required will be custom-made for us, which will lead to long lead times and expedited procurement to meet our timelines. In addition, it may take longer than anticipated to scale up our facilities and to complete our Marlborough, Massachusetts facility (which we expect to dedicate to INTs) to meet commercial demand, if our INT product candidate is approved. This expansion and addition of new facilities could also lead to product comparability issues, which could further delay introduction of new capacity.

Because our INTs are manufactured for each individual patient, we are required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, results of analysis of such patient's genomic analysis and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so has resulted and may in the future result in product mix up, adverse patient outcomes, loss of product or regulatory action, including withdrawal of any approved products from the market. Further, as our INTs are developed through clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery process will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our INTs to perform differently than we expect, potentially affecting the results of clinical trials.

Risks related to our reliance on third parties

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our products and product candidates.

We depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop and commercialize, our products and product candidates. We cannot ensure that these suppliers will remain in business, have

sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that will cease working with us. Our use of single-source suppliers exposes us to several risks, including disruptions in supply, price increases, late deliveries or business interruptions.

There are, in general, few alternative sources of supply for substitute components. If we have to switch suppliers, the manufacture and delivery of our products or product candidates could be interrupted for an extended period. Establishing additional or replacement suppliers for any of the components or processes used in our products or product candidates, if required, may not be accomplished quickly, if at all. Any replacement supplier (or us, if we produced directly) would need to be qualified and may require additional regulatory authority approval, resulting in further delay. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our products or product candidates. Additionally, as part of the FDA's approval of our product candidates, the FDA will review the manufacturing processes and facilities of our single-source suppliers.

We have entered into, and in the future may enter into, strategic alliances with third parties for the development and commercialization of products and product candidates. If these strategic alliances are not successful, our business could be adversely affected.

We have entered into strategic alliances with collaborators that have provided, and may in the future provide, funding, intellectual property licenses and other resources for developing, manufacturing and commercializing our product candidates. Additionally, we have entered into, and expect to enter into future, strategic alliances where we agree to provide funding, intellectual property licenses and other resources to third parties. Our existing and any future strategic alliances may pose a number of risks, including:

- strategic collaborators may not perform their obligations as expected;
- strategic collaborators may not pursue development and commercialization of any products that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators' focus or available funding or external factors that divert resources or create competing priorities;
- strategic collaborators may delay clinical trials, provide insufficient funding or resources for clinical trials (whether as a result of a business decision or necessitated by financial difficulties of such collaborator), stop a clinical trial, abandon a product candidate or repeat or conduct new clinical trials;
- products or product candidates developed in strategic alliances with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause them to cease to devote resources to development or commercialization;
- a strategic collaborator with marketing and distribution rights to one or more of our products may commit insufficient resources to the marketing and distribution of any such product;
- disagreements with strategic collaborators, including over proprietary rights, contract interpretation or the course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, lead to additional responsibilities for us with respect to such product candidates or result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic collaborators may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our IP or proprietary information;
- disputes may arise with respect to the ownership of IP developed pursuant to our strategic alliances;
- strategic collaborators may infringe the IP rights of third parties, exposing us to potential litigation and liability;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business;
- any equity investments we make in collaborators could decrease in value or become worthless; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States.

Our strategic collaborators generally may materially amend or terminate their agreements with us, which has happened in the past. If any collaboration agreement is terminated, we may not receive anticipated future research or development funding or milestone, earn-out royalty, profit share or other contingent payments and the research or development of our product candidates may be delayed or discontinued. It may also be difficult to attract new strategic collaborators to continue development or commercialization of the applicable product candidate, and our reputation could be adversely affected. All the risks relating to product development, regulatory approval and commercialization described elsewhere in these Risk Factors apply to our strategic collaboration activities.

We may seek to establish additional strategic alliances and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of some of our product candidates, and we face significant competition in seeking appropriate strategic collaborators. Our ability to establish additional strategic alliances will depend, among other things, on our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed strategic alliance and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to trial participants, the potential of competing drugs, the existence of uncertainty with respect to our or the proposed collaborator's ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally.

We are also restricted under some of our existing strategic alliance agreements from entering into agreements on certain terms with potential strategic collaborators to pursue other targets on our own. These restrictions on working with targets, polypeptides, routes of administration and fields could limit our ability to enter into strategic collaborations with other collaborators or to pursue certain potentially valuable product candidates.

Strategic alliances are complex and time-consuming to negotiate and document. If we cannot enter into new strategic alliances on a timely basis, on favorable terms or at all, we may need to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

We rely on and expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, protocol development and clinical trials for our product candidates. If these third parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties such as CROs to help manage certain preclinical work and our clinical trials, and on medical institutions, clinical investigators and CROs to assist in the design and review of, and to conduct, our clinical trials, including enrolling qualified patients. In addition, we engage third-party contractors and collaborators to support numerous other research, commercial and administrative activities, which reduces our control over these activities but does not relieve us of our responsibilities, such as ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocols. Moreover, the FDA requires us to comply with GLPs and good clinical practices for conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that in the case of clinical trials the rights, integrity and confidentiality of trial participants are protected. Such standards will evolve and subject us and third parties to new or changing requirements.

If third parties do not successfully carry out their contractual duties or meet expected deadlines, we may need to replace them, which could cause a delay of the affected clinical trial, drug development program or applicable activity. If clinical trials are not conducted in accordance with our contractual expectations or regulatory requirements, action by regulatory authorities may significantly and adversely affect the conduct or progress of such trials or even require a clinical trial to be redone. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates could be delayed. In addition, failure of any third-party contractor to conduct activities in accordance with our expectations could adversely affect the relevant research, development, commercial or administrative activity. Failure of any third-party contractor to timely provide access to our data in a format that is acceptable to us may result in delays or impediments to our regulatory submissions or other development activities.

Risks related to our intellectual property

We may be unable to obtain and enforce patent protection for our discoveries and the intellectual property rights therein, or protect the confidentiality of our trade secrets.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other IP laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. Because certain U.S. patent applications are confidential until the patents issue, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, if at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or

pending patent applications or that we were the first to file for patent protection of such inventions. We therefore may be unable to secure desired patent rights, thereby losing exclusivity. In the past, we have obtained licenses under third-party patents to market our products or conduct our research and development or other activities, and we may do so in the future if necessary. If licenses are not available to us on favorable terms, we may not be able to market the affected products or conduct the desired activities.

The process of obtaining and enforcing patent protection is expensive and time-consuming and our pending patent applications may not result in issued patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent applications may fail to result in valid enforceable patents, or our patent protection could be reduced or eliminated, for non-compliance with these requirements. If we or our strategic collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business may be adversely affected.

Despite our and our strategic collaborators' efforts to protect our proprietary rights, unauthorized parties may obtain and use information that we regard as proprietary. While issued patents are presumed valid, they may not survive a validity challenge and could be held unenforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, adjudged unenforceable or circumvented by parties seeking to design around our IP. Also, third parties or the USPTO may commence patent office proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation, or circumvention of, our patents or patent applications, would be costly, would require significant time and attention of our management, could reduce or eliminate royalty payments to us from third-party licensors and could have a material adverse impact on our business.

The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and foreign countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. For example, the America Invents Act included a number of changes to the patent laws of the United States. If any of the enacted changes prevent us from adequately protecting our discoveries, including our ability to pursue infringers of our patents to obtain injunctive relief or for substantial damages, our business could be adversely affected. One major provision of the America Invents Act changed U.S. patent practice from a first-to-invent to a first-to-file system. If we fail to file an invention before a competitor files on the same invention, we no longer have the ability to provide proof that we were in possession of the invention prior to the competitor's filing date, and thus would not be able to obtain patent protection for our invention. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable.

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. We also rely to a certain extent on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We also rely on non-disclosure agreements and invention assignment agreements entered into with our employees, consultants and third parties. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

Failure to obtain and maintain all available regulatory exclusivities and broad patent scope and to maximize patent term restoration or extension on patents covering our products may lead to loss of exclusivity and early biosimilar entry resulting in a loss of market share or revenue.

In addition, we may choose not to enforce our IP rights in certain circumstances or for certain periods of time. For example, in March 2022, we announced that we will not enforce our patents for COVID-19 vaccines against companies manufacturing in or for the Gavi COVAX Advance Market Commitment countries, provided that the manufactured vaccines are solely for use in the AMC 92 countries. In addition, we are willing to license our IP for COVID-19 vaccines to manufacturers, but we may never enter into such licenses of our IP, and our business may be otherwise adversely impacted if we are unable to enforce our IP.

Uncertainty over IP in the pharmaceutical and biotechnology industry has been the source of litigation and other disputes, which is inherently costly and unpredictable and can have adverse financial and freedom-to-operate consequences.

mRNA medicines are a relatively new scientific field and, as the field continues to mature, patent applications are being processed by national patent offices globally. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. Litigation is ongoing over the underlying technology to mRNA medicines between many mRNA market participants. It is likely that there will continue to be significant litigation and patent office proceedings in various patent offices relating to patent rights in the mRNA field.

We have issued patents and pending patent applications in the United States and in key markets around the world that claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of mRNA medicines and our delivery technology, including LNPs. Oppositions and inter partes review petitions have been filed against some of our patents, and we expect that further proceedings will be filed in the European Patent Office (EPO), USPTO and elsewhere relating to patents and patent applications in our portfolio. In many cases, the possibility of appeal exists for any party, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. We cannot be certain that any patent will survive or that the claims will remain in the current form. Even if our rights are not directly challenged, disputes could lead to the weakening of our IP rights.

In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of mRNA medicines. We have a number of these proceedings ongoing against third-party patents. If we are unsuccessful in narrowing or invalidating such third-party patents, those third parties may attempt to assert those patents against our products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products or product candidates may be subject to claims of infringement of the patent rights of third parties.

We have invested billions of dollars in creating our patented mRNA platform, which is integral to the development of our mRNA medicines, and we are involved in various intellectual property litigation as described under Part I, Item 3, "Legal Proceedings." We expect to expend substantial financial and managerial resources in connection with these legal proceedings, and the ultimate outcome of each proceeding is uncertain.

We are, and may in the future become, involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and product candidates, and third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires.

Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and divert employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

In addition, any such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability, which could jeopardize our ability to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our IP may be offset by amounts paid by our collaborators to third parties who have competing or superior IP positions in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and strategic alliance agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to IP rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to IP rights, even if resolved in our favor, could be substantial, and litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could delay our research, development and commercialization efforts and limit our ability to continue our operations.

If third-party owners of any patent rights that we license do not properly or successfully obtain, maintain or enforce the patents underlying such licenses, our competitive position and business prospects may be harmed.

We may become a party to licenses that give us rights to third-party IP that is necessary or useful for our business. In such a case, our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed IP. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the IP we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our strategic collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our strategic alliance agreements or result in termination of an agreement by one or more of our strategic collaborators.

If we fail to comply with our obligations in the agreements under which we license IP rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We license IP, which involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. We are a party to certain IP license agreements and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license and may be subject to additional liabilities.

In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our strategic collaborators. Disputes may arise regarding IP subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether our technology and processes that are not subject to the licensing agreement infringe on IP of the licensor;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of IP by our licensors and us and our strategic collaborators; and
- the priority of invention of patented technology.

If disputes over IP that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of IP that we license as we are for IP that we own. If we or our licensors fail to adequately protect this IP, our ability to commercialize products could suffer.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. From time to time, we are subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed IP, including trade secrets or other proprietary information, of third parties, including our employees' former employers. Litigation may be necessary to defend against these claims. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable IP rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other IP.

We may be and have been subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other IP. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP

rights, including exclusive ownership of, or right to use, valuable IP. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract management and other employees, and could impact or patenting strategy.

Changes in U.S. patent and regulatory law could impair our ability to protect our products.

Our success is heavily dependent on IP, particularly patents. U.S. patent law continues to evolve, and certain U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have increased uncertainty with regard to our ability to obtain patents in the future, as well as with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be unable to protect our IP rights throughout the world.

Filing, prosecuting and defending patents in every country would be prohibitively expensive, and our foreign IP rights can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect IP rights to the same extent as U.S. federal and state laws. Consequently, we may be unable to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection or may export infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States.

Many companies have encountered significant problems in protecting and defending IP rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other IP protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our IP rights around the world may be inadequate to obtain a significant commercial advantage from the IP that we develop or license.

Additionally, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, during the COVID-19 pandemic, certain countries threatened steps to facilitate compulsory licenses to permit the distribution of a COVID-19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Our reliance on government funding and collaboration from governmental and quasi-governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements related to intellectual property rights and requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;

- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us and we may be unable to prohibit other companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs and environmental compliance requirements.

Further, under these agreements we are subject to the obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980 (Bayh-Dole Act). As a result, the U.S. government may have rights in certain inventions developed under these government-funded programs, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Any exercise of the march-in rights by the U.S. government could harm our competitive position, business, financial condition, results of operations and prospects. In December 2023, the Biden administration released a proposed framework specifying for the first time that price can be a factor in considering whether an invention is sufficiently available to the public. The proposed framework could potentially enable march-in rights to be used as a tool to regulate drug pricing. The potential inclusion of price as a factor in a march-in determination is expected to draw extensive criticism and challenge, and the ultimate impact is currently unknown. If the U.S. government exercises such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market. IP generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

As an organization, we are relatively new to government contracting and the related regulatory compliance obligations. If we fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts.

Risks related to our financial condition and results of operations

We incurred net losses in 2023 and we may incur losses again in the future; we have a limited history of recognizing revenue from product sales and may be unable to achieve long-term sustainable profitability.

We incurred a net loss of $4.7 billion in 2023, and other than in 2021 and 2022, we have incurred net losses in each year since our inception. Currently, our COVID-19 vaccine is our only commercial product. While preparations are underway for additional potential product launches, including our anticipated RSV launch in 2024, the ultimate occurrence and timing of these launches is uncertain. Our ability to generate revenue and maintain profitability depends on our ability to successfully develop and obtain the regulatory approvals necessary to commercialize our products.

We have incurred, and expect to continue to incur, significant costs associated with commercializing our COVID-19 vaccine and our clinical and preclinical development activities. In addition, we incurred significant costs in 2023 as we resized our manufacturing capacity. We may be unable to achieve long-term sustainable profitability and may need additional funding to continue operations.

We anticipate that our expenses may increase substantially if and as we:

- expand our research or development of our programs in preclinical development;
- initiate additional preclinical, clinical or other studies for our product candidates, particularly large pivotal trials;
- continue to invest in our platform to conduct research to identify novel mRNA technology improvements;
- change or add to internal manufacturing capabilities, or additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and commercialization efforts, including new sites globally;
- seek marketing approvals and reimbursement for our product candidates;
- build out a sales, marketing and distribution infrastructure to commercialize any products;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements; and
- experience any delays or encounter issues with any of the above.

Our quarterly and annual operating results may fluctuate. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as our ability to exist as a standalone company.

Our financial condition and operating results may fluctuate from quarter-to-quarter and year-to-year due to many factors, many of which are beyond our control. As such, a period-to-period comparison of our operating results may not be predictive of our future performance. In any particular quarter, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. Our stock price could be affected by events not necessarily tied to our actual operating results, including recommendations by securities analysts, the timing of certain public disclosures by us, our collaborators or our competitors and our ability to accurately report our financial results in a timely manner. Other factors relating to our business that may contribute to these fluctuations include those described in these *Risk Factors* and elsewhere in this Annual Report on Form 10-K.

The investment of our cash, cash equivalents and investments is subject to risks which may cause losses and affect the liquidity of these investments.

As of December 31, 2023, we had approximately $13.3 billion in cash, cash equivalents and investments, which are subject to general credit, liquidity, market, inflation and interest rate risks. We may realize losses in the fair value of these investments. In addition, if our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These and other market risks associated with our investment portfolio may adversely affect our results of operations, liquidity and financial condition.

Risks related to our business and operations

We may encounter difficulties in managing the development and expansion of our company.

As of December 31, 2023, we had approximately 5,600 full-time employees in 19 countries, and we may increase our number of employees and the scope of our operations. To manage this global expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train qualified personnel. Our management may need to divert significant attention away from our day-to-day activities to manage these development activities.

Successfully developing products for and fully understanding the regulatory and manufacturing pathways for the many therapeutic areas and diseases we seek to address requires significant depth of talent, resources and corporate processes to allow simultaneous execution across multiple areas. We may be unable to effectively manage this simultaneous execution and expansion of our operations or recruit and train qualified personnel, which could cause weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations, including the expansion of our Norwood and Marlborough campuses in Massachusetts and the construction of manufacturing facilities overseas, may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our development and expansion, our financial performance and ability to commercialize our products may be affected negatively, and we may not be able to implement our business strategy.

We are subject to the risks of doing business outside of the United States.

Our business is subject to risks associated with doing business outside of the United States, and we have limited experience operating internationally. We are not permitted to market or promote any of our product candidates before we receive regulatory approval or other authorization from an applicable authority, and we may never receive such approval. To obtain regulatory approval in various jurisdictions, we must comply with numerous regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our product candidates, and we may fail to obtain approval. We have rapidly expanded our global operations, establishing commercial subsidiaries and entering into arrangements to support the worldwide manufacture and distribution of our products, which is a complex task. For example, we are building regional manufacturing facilities and investing in research and development in several countries. Our business may be adversely affected by many factors associated with our expanding global business, including:

- efforts to develop an international commercial sales, marketing and supply chain and distribution organization, including efforts to mitigate longer accounts receivable collection times, longer lead times for shipping and potential language barriers;
- our customers' ability to obtain reimbursement for our products in foreign markets;
- our inability to directly control commercial activities because we rely on third parties;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- changes in a specific country's or region's political and cultural climate or economic condition;
- an increased legal and compliance burden to establish, maintain and operate legal entities in foreign countries;
- the burden of complying with complex and changing foreign regulatory, tax, accounting, reporting and legal requirements, including the European General Data Protection Regulation 2016/679 (GDPR);
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute, and the difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate IP protection in foreign countries and the existence of potentially relevant third-party IP rights;
- trade-protection measures including trade restrictions, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties, or suspension or revocation of export privileges, the imposition of government controls and changes in tariffs;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates.

We are also subject to extensive federal, state and foreign anti-bribery regulations, including the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act and similar laws in other countries. Compliance with the FCPA is expensive and difficult, particularly in countries where corruption is a recognized problem. Additionally, the FCPA presents particular challenges to the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, we will need to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

We cannot guarantee that we, or our employees, consultants or third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our strategic collaborators and third-party contractors outside the United States may have inadequate compliance programs or fail to respect the laws and guidance of the territories where they operate, which may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Even if we are not determined to have violated these laws, government investigations typically require the expenditure of significant resources and generate negative publicity, which could adversely affect our business, financial condition and results of operations.

Our failure to upgrade and maintain our enterprise resource planning (ERP) system could adversely impact our business and results of operations.

We are upgrading our global ERP system to support our continued growth as a commercial operation. We have incurred substantial costs in implementing our ERP system, and any disruptions or difficulties in implementing or using our system could adversely affect our controls, resulting in harm to our business, including our ability to forecast or make sales and collect our receivables. Significant delays in documenting, reviewing and testing our internal controls could cause our non-compliance with our SEC reporting obligations related to our management's assessment of our internal control over financial reporting. Moreover, such disruptions or difficulties could result in unanticipated costs and diversion of management's attention.

Our success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends on our ability to attract and retain highly qualified managerial, scientific, technical, quality-control, manufacturing, medical, regulatory and commercial personnel. The turnover rate in our industry is high and we compete with other companies, as well as academic institutions, for individuals with certain skill sets. Failure to attract and retain personnel could result in delays in production or difficulties in maintaining compliance with regulatory requirements. In addition, adverse publicity, including as the result of failure to succeed in clinical trials or obtain marketing approvals, may make it difficult to recruit and retain qualified personnel.

We are highly dependent on members of our management and scientific teams. Each of our executive officers and employees, including key scientists and clinicians, are employed "at will," meaning we or they may terminate the employment relationship at any time. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We do not have "key person" insurance on any of our employees. Several of our key employees, including executives, have been with us for a long period of time, and have valuable, fully vested stock options or other long-term equity incentives. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in Cambridge, Massachusetts.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to help us formulate our research and development, regulatory approval, manufacturing and commercialization strategies. These individuals may be employed by other employers and may have commitments under contracts with others that limit their availability to us. The loss of the services of these individuals might impede the achievement of our research, development, regulatory approval, manufacturing and commercialization objectives.

If we cannot maintain our corporate culture, we could lose the innovation, teamwork and passion that we believe contribute to our success.

We invest substantial time and resources in building and maintaining our culture and developing our personnel; however, as we continue to expand, it may be increasingly difficult to maintain our culture. The dramatic growth of our workforce, coupled with recent shifts in workplace and workstyle, increase the risk of our ability to maintain culture. Any failure to preserve our culture could negatively affect our future success, including our ability to retain and recruit personnel and to effectively pursue our strategic plans.

Our internal computer systems and physical premises, or those of third parties with which we share sensitive data or information, may fail or suffer security breaches, including from cybersecurity incidents, which could materially disrupt our product development programs and manufacturing operations.

Our internal computer systems and infrastructure and those of our strategic collaborators, vendors, contractors, consultants or regulatory authorities with whom we share confidential, protected or sensitive data or information, or upon which our business relies, are vulnerable to damage from computer viruses, unauthorized access, misuse, natural disasters, terrorism, cybersecurity threats, war and telecommunication and electrical failures, as well as security compromises or breaches, which may compromise our systems, infrastructure, data or that of those with whom we share such data or information or upon which our business relies, or lead to data compromise, misuse, misappropriation or leakage. We have experienced, and may experience additional, cyber-attacks on our information technology systems and infrastructure by threat actors of all types (including nation states, criminal enterprises, individual actors or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by these threat actors. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, digital extortion, business email compromise and denial-of-service attacks, social engineering and other means to affect server reliability and threaten the confidentiality, integrity and availability of information, systems or infrastructure. If any such cyber-attack or physical intrusion against us or those with whom we share confidential, protected or sensitive data or information, or upon which our business

relies, were to result in a loss of or damage to our data, systems or infrastructure, or interrupt our operations, such as a material disruption of our development programs or our manufacturing operations, or due to a loss of any of our proprietary or confidential information, it would have a material adverse effect on us. For example, the loss of clinical trial data could delay our regulatory approval efforts and increase our costs to recover or reproduce the data. In addition, because we run multiple clinical trials in parallel, any breach or compromise of our computer systems or infrastructure or physical premises may result in a loss of data or compromised data integrity across multiple programs in many stages of development. While we seek to take steps to address cybersecurity risks, our efforts may not wholly mitigate such risks. Further, our cybersecurity liability insurance may not cover all damages we would sustain based on any breach or compromise of our computer security protocols or cybersecurity attack.

Any data breach, security incident or compromise of confidential, protected or personal information, including any clinical trial participant personal data, may also subject us to civil fines and penalties, litigation, regulatory investigations or enforcement actions, or claims for damages under the GDPR and UK GDPR and relevant member state law in the EU, other foreign laws, and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the CCPA). We have from time to time received information that companies working on vaccine research and development may be a particular focus for those planning cyberattacks, including by nation states and affiliated cyber actors. To the extent that any disruption or security compromise incident or breach were to result in a loss of, or damage to, our data, systems, infrastructure or applications, or inappropriate use or disclosure of confidential or proprietary information, including information related to the research and manufacturing of our products, we could incur liability, our competitive and reputational position could be harmed and the further development and commercialization of our product candidates could be delayed.

We may use our financial and human capital to pursue a particular research program or product candidate and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

We pursue and fund the development of selected research programs or product candidates and may choose to forego or delay pursuit of other opportunities that could later prove to have greater commercial potential. For example, we have focused a significant amount of resources on our COVID-19 vaccines and other respiratory programs, for which preparations are underway for multiple vaccine launches. Additionally, we are increasing our investments in our INT programs. Our resource allocation decisions, or our contractual commitments to provide resources to our strategic collaborators, may cause us to fail to capitalize on certain commercial products or profitable market opportunities. Our spending on research and development programs for product candidates may not yield commercially viable products. We may also seek to enter into strategic collaborations or financing arrangements pursuant to which we may relinquish valuable rights to product candidates, including the rights to a portion of future revenues, through a strategic alliance, licensing or other royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights. Additionally, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a strategic alliance.

If we are not successful in discovering, developing and commercializing additional products, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop and commercialize products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our drug discovery efforts, exploring potential strategic alliances for the development of new products and in-licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources. We may fail to identify promising candidates or to successfully develop and commercialize products for many reasons, which would impair our potential for growth.

Our business could be harmed if we suffer damage to our reputation, including as a result of a product recall.

The FDA or foreign regulators could require the recall of our products. The FDA has authority to recall a biologic product if it finds that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, foreign governmental bodies may require the recall of any products in the event of material deficiencies or defects in design or manufacture. Manufacturers may independently recall a product if a material deficiency in a product is found. A government-mandated or voluntary recall by us or our strategic collaborators could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues, as occurred with the recall in 2021 of certain batches of our COVID-19 vaccine shipped to Japan that were found to contain foreign particulate. Recalls of any of our products would divert managerial and financial resources and adversely affect our financial condition and results of operations. A recall announcement could harm our reputation and negatively affect our sales. Our reputation could be further impacted by public discourse regarding our business and perception of our business strategy.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our products.

We are exposed to product liability risk related to the development, testing, manufacturing and marketing of our products and product candidates in clinical trials. Product liability claims and related cross-claims and claims for indemnification may be brought against us by patients, healthcare providers or others using, prescribing, selling or otherwise coming into contact with our products or product candidates. For example, we may be sued if any product or product candidate allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing or, if approved, marketing, sale or commercial use. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities.

We could also face product liability claims relating to the worsening of a patient's condition, injury or death alleged to have been caused by our products or product candidates. Any such claims may include allegations of defects in manufacturing or design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, knowledge of risks, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims might not be fully covered by product liability insurance. For any marketed products, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, suspension or withdrawal of approvals or license revocation. Regardless of the merits or eventual outcome, liability claims may cause decreased demand for our products, injury to our reputation and significant negative media attention, costs to defend the related litigation, withdrawal of clinical trial participants, loss of revenue, a diversion of management's time and our resources, substantial monetary awards to trial participants, patients or their family members, payments to indemnify clinical trial sites and other clinical trial partners and a decline in our stock price. On occasion, large judgments have been awarded in individual, mass tort and class-action lawsuits based on drugs or medical treatments that had unanticipated adverse effects.

With respect to our COVID-19 vaccine, although the U.S. and certain foreign governments have contractually agreed to indemnify us or make statutory immunity available to us, such indemnification or statutory immunity may be unavailable to cover potential claims or liabilities resulting from the research, development, manufacture, distribution or commercialization of the vaccine. Additionally, other foreign governments that we contract with may not provide us with similar contractual indemnity or statutory immunity, and we will not have the benefit of such indemnities or immunities in the future as the COVID-19 vaccine market transitions to a commercial market in the United States and elsewhere. Substantial claims arising from the vaccine outside the scope of or in excess of U.S. or foreign government indemnity or statutory immunity could harm our financial condition and operating results. Moreover, any adverse event or injury for which we are liable, even if fully covered under an indemnity or immunity, could negatively affect our reputation.

We may be unable to maintain our product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

Federal legislation and actions by federal, state and local governments may permit reimportation into the United States of drugs from foreign countries where the drugs are sold at lower prices.

We may face competition in the United States for our products from therapies sourced from foreign countries with price controls on pharmaceutical products. For example, in October 2020, the FDA published a final rule that would allow for the importation of certain prescription drugs from Canada, where there are government price controls. In January 2024, the FDA approved Florida's request to import certain lower-priced medications from Canada. While the full implications of the final rule are currently unknown, legislation or regulations allowing the reimportation of drugs could decrease the price we receive for any products we may develop and adversely affect our future revenues and potential profitability.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

In the United States, federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the ACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the PHSA. Additionally, the Inflation Reduction Act of 2022 includes several provisions such as drug pricing controls and Medicare redesign that are likely to impact our business to varying degrees, but its ultimate effect on our business and the healthcare industry in general is not yet known. See "Business—Government Regulation-Current and future healthcare reform legislation."

We may face uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. There is no assurance that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There is increasing public attention on the costs of prescription drugs and there have been, and are expected to continue to be, legislative proposals to address prescription drug pricing, which could have significant effects on our business. These actions and the uncertainty about the future of the ACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs or that would allow for importation of pharmaceutical products from lower cost jurisdictions outside the United States. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding limitation on prices and reimbursement for our products, if approved.

In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures, and may in the future implement new or additional measures, to reduce health care costs to limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries. These measures may adversely affect our revenues and results of operations.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and false claims laws. If we cannot comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. See "Business—Government Regulation—Other healthcare laws."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable

healthcare laws, as well as responding to possible investigations by government authorities, is time- and resource-consuming and can divert a company's attention from the business. If our operations are found to violate any of these laws or any other regulations, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance. Furthermore, if any physician or other healthcare provider or entity with whom we do business is found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate we develop outside the United States will subject us to foreign healthcare laws.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU and the UK. The provision of benefits or advantages to induce or reward improper performance generally is also governed by the national anti-bribery laws of EU Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. The EU Directive (2001/83/EC, as amended) governing medicinal products for human use provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often are the subject of prior notification and approval by the physician's employer, his or her competent professional organization, or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are subject to various and evolving laws and regulations governing the privacy and security of personal data, and our failure to comply could result in fines or criminal penalties and damage our reputation.

Privacy and data security are significant issues in the United States, Europe and many other jurisdictions where we operate or collect personal information. We are subject to data privacy and security laws and regulations in various jurisdictions that apply to the collection, storage, use, sharing and security of personal data, including health information, and impose significant compliance obligations. In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection and privacy laws, govern the collection, use, disclosure and security of personal information.

The GDPR and UK GDPR impose stringent obligations on us with respect to our processing and the cross-border transfer of personal data, including higher standards of obtaining consent or ensuring another appropriate legal basis or condition applies to the processing of personal data, more robust transparency requirements, data breach notification requirements, requirements for contractual language with our processors and stronger individual data rights. Different EEA Member States have interpreted the GDPR differently and many have imposed additional requirements, adding to the complexity of processing personal data in the EEA. The GDPR and UK GDPR also impose strict rules on the transfer of personal data to countries outside the EEA that are not considered to provide "adequate" protection to personal data, including the United States, and permits data protection authorities to impose large penalties for violations. Compliance with the GDPR and UK GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices. We could be subject to fines and penalties, litigation and reputational harm in connection with any activities falling within the scope of the GDPR or UK GDPR.

In the United States, California has passed the CCPA and numerous other states have passed their own similar comprehensive consumer privacy laws. There are also states that are specifically regulating health information. Further, a small number of states have passed laws that regulate biometric data specifically. In addition, numerous states and the federal government are actively considering proposed legislation governing the protection of personal data. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

Additionally, many foreign jurisdictions have passed data privacy legislation and others are considering various proposals for new privacy and data protection laws. Data privacy remains an evolving landscape at the domestic and international levels, with new laws and regulations being considered and coming into effect and continued legal challenges. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and regulatory agencies, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant

penalties if we are found to be non-compliant. Some of these laws and regulations also carry the possibility of criminal sanctions. For example, we could be subject to penalties, including criminal penalties, if we knowingly obtain or disclose individually identifiable health information from a HIPAA-covered health care provider or research institution that has not complied with HIPAA's requirements for disclosing such information. Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and our reputation.

The Clinical Trials Regulation (EU) No. 536/2014 (the Clinical Trial Regulation) and the EMA policy on publication of clinical data for medicinal products for human use both permit the EMA to publish clinical information submitted in MAAs. The ability of third parties to review or analyze data from our clinical trials may increase the risk of commercial confidentiality breaches and result in enhanced scrutiny of our clinical trial results. Such scrutiny could result in public misconceptions regarding our drugs and drug candidates. These publications could also result in the disclosure of information to our competitors that we might otherwise deem confidential, which could harm our business.

Our use of GenAI and other AI technologies presents certain risks and challenges given the emerging nature of AI technologies.

The development and use of GenAI and other AI technologies (collectively, AI Technologies), along with an uncertain regulatory landscape, pose risks that could harm our reputation, expose us to liability or adversely affect our business. The integration of AI Technologies into our and our vendors' systems (potentially without the vendor disclosing such use to us) subjects us to the risk that the providers of AI Technologies may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection. This may lead to breaches of security or privacy, reduced levels of service or experience, loss of intellectual property or exposure of confidential or proprietary information. Sophisticated cyber-attacks, including those using AI, could exacerbate these risks. Additionally, GenAI's potential for producing false or misleading outputs, reflecting biases or generating content that may not be subject to intellectual property protection or that infringes proprietary rights of others, poses additional risks to our business. Regulatory changes or reinterpretations could introduce new compliance risks, including potential government enforcement actions or civil lawsuits. Our competitors' faster or more effective adoption of AI could also disadvantage us.

We could be adversely affected by outbreaks of epidemic, pandemic or other contagious diseases.

In the event of a future epidemic or pandemic, our clinical trials could be paused or delayed due to restrictions (such as quarantines or travel limitations) or reprioritization of resources. Travel limitations could also create challenges and potential delays in our development and production activities, increasing the expense and timelines for producing our products and product candidates.

We utilize third parties to, among other things, manufacture raw materials, components, parts and consumables, perform quality testing and ship our products. If these third parties were to experience delays or disruptions in providing their services in response to an epidemic or pandemic, our supply chain could be disrupted, limiting our ability to manufacture and sell our products and manufacture product candidates for our clinical trials, as well as negatively impacting our research and development operations. Such delays or disruptions could adversely impact our strategic collaborators' ability to fulfill their obligations, which could affect the clinical development or regulatory approvals of product candidates under joint development.

In addition, during a global health crisis, one or more government entities could take actions (such as via the Defense Production Act in the U.S.) that diminish our rights or economic opportunities with respect to our products. Our third-party service providers could be impacted by government-imposed restrictions on services they might otherwise offer. Any such action could cause us to experience delays in the development, production, distribution or export of our products and product candidates and increased expenses.

Engaging in acquisitions, joint ventures or strategic collaborations may increase our capital requirements, dilute our stockholders and cause us to incur debt or assume contingent liabilities.

We may engage in acquisitions, joint ventures and collaborations, including licensing or acquiring complementary products, IP rights, technologies or businesses. Such transactions and relationships may entail numerous risks, including:

- increased operating expenses and cash requirements;
- assimilation of operations, IP and products, including difficulties associated with integrating new personnel;
- the diversion of management's attention from our existing product programs and initiatives;
- the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

If we undertake acquisitions, we may utilize cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, if we cannot locate suitable acquisition or strategic collaboration opportunities, our ability to grow or obtain access to technology or products that may be important to the development of our business may be impaired.

The illegal distribution and sale by third parties of counterfeit or stolen versions of mRNA products, or the unauthorized donation or re-sale of mRNA products, could negatively impact our financial performance or reputation.

Third parties could illegally distribute and sell, especially online, counterfeit versions of mRNA products that do not meet the rigorous cGMP manufacturing and testing standards. Counterfeit medicines may contain harmful substances or the wrong dose, are frequently unsafe or ineffective and could be life-threatening. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting or unsafe mRNA products could materially affect patient confidence in our mRNA products. Adverse events caused by unsafe counterfeit or other non-mRNA products could mistakenly be attributed to our mRNA products. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business. Public loss of confidence in the integrity in mRNA products as a result of counterfeiting, theft or improper manufacturing processes could have a material adverse effect on our business, results of operations and financial condition. Further, the unauthorized donation or resale of our product could adversely affect our ability to sell in a particular territory, and have other adverse effects on our business, results of operations and financial condition.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations and financial condition.

We are exposed to physical risks (such as rising temperatures, flooding and severe storms), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in customer behavior and cost and availability of raw materials) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term). Climate-related physical risks to our facilities and those of our suppliers could disrupt our operations and supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could subject us to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, investments in data gathering and reporting systems, upgrades of facilities to meet new building codes and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy we use. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us, which may affect our ability to procure raw materials or other supplies required to operate our business at the quantities and levels we require.

Our aspirations, goals and disclosures related to environmental, social and governance (ESG) matters expose us to numerous risks.

Institutional and individual investors are increasingly using ESG screening criteria to determine whether we qualify for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ambitious ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. Statements about these goals reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives, including with respect to environmental and diversity initiatives, are subject to numerous risks, many of which are outside of our control, which could have a material negative impact, including on our reputation and stock price.

Further, the standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquiror could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous and flammable materials and wastes, including chemicals and biological materials. We generally contract with third parties for the disposal of these materials and waste products, and we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines, penalties or other sanctions for failure to comply with such laws and regulations. We may also incur substantial costs to comply with such laws and regulations, and these laws and regulations could impair our research, development or production efforts.

Our workers' compensation insurance may not provide adequate coverage against potential liabilities due to injuries to our employees resulting from the use of hazardous materials. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Risks related to ownership of our common stock

The price of our common stock has been volatile, which could result in substantial losses for stockholders.

Our stock price has been, and is expected to continue to be, subject to substantial volatility. Since our IPO in December 2018, our stock price has ranged from a high of $497.49 to a low of $11.54 per share. Since we began our COVID-19 vaccine development efforts in early 2020, our stock has experienced pronounced and extended periods of volatility, which could cause our stockholders to incur substantial losses. Public statements by us, government agencies, the media, competitors, financial analysts or others relating to COVID-19 have resulted, and may result, in significant fluctuations in our stock price. Information in the public arena on this topic, whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price.

The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies, and you may not be able to sell your shares at or above your initial purchase price. The market price for our common stock may be influenced by many factors, including:

- our COVID-19 vaccine sales and anticipated product revenue;
- the commercial launch of any additional products;
- timing and results of clinical trials or progress of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- the emergence or decline of new or existing variants of the SARS-CoV-2 virus;
- developments regarding our manufacturing, regulatory and commercialization efforts, or information regarding such efforts by competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- expenses related to any of our products or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates of financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- economic, industry and market conditions generally, and in the biopharmaceutical sector specifically; and
- announcement by us or our competitors of the commencement or termination of significant acquisitions, strategic partnerships, joint ventures or capital commitments.

Securities class-action litigation often has been instituted against companies following periods of volatility in their stock price. If such litigation were instituted against us, we could incur substantial costs in defense and management's attention and resources could be diverted, which could adversely affect our business, financial condition and results of operations and prospects.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 16, 2024, our executive officers, directors and affiliated stockholders owned, directly or indirectly, approximately 12% of our outstanding common stock. In addition, non-affiliated five percent or greater stockholders owned approximately 27% of our outstanding common stock. These stockholders will have the ability to influence us through their ownership positions. For example, if they were to act together, they could exert significant influence over matters such as elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may believe to be in their best interests.

Provisions in our organizational documents, as well as provisions of Delaware law, could make it more difficult or costly for a third party to acquire us or remove our current management, even if doing so would benefit our stockholders.

Our amended and restated certificate of incorporation (charter), amended and restated by-laws (by-laws) and Delaware law contain provisions that could delay or prevent a hostile takeover or change in control of us or changes in our management. Our charter and by-laws include provisions that:

- authorize "blank check" preferred stock, which could be authorized for issuance by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our charter and by-laws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Any provision of our charter, by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares, and could also affect the price that some investors are willing to pay for our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business or to return cash to shareholders through share repurchases. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our by-laws designate the Court of Chancery of the State of Delaware or the U.S. District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to by-laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law or our by-laws or (4) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our by-laws further provide that the U.S. District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising

under the Securities Act (the Federal Forum Provision). Our by-laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our by-laws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is unenforceable or invalid, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs in resolving such matters. The Court of Chancery of the State of Delaware and the U.S. District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General risk factors

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators leading our clinical trials and consultants. Such misconduct could include failures to comply with FDA regulations or similar regulations in other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad or report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve improper use of information obtained during clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and serious harm to our reputation. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter employee misconduct, and we may fail to control unknown or unmanaged risks or losses or take steps that protect us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including through the imposition of significant fines or other sanctions.

Unfavorable U.S. or global economic conditions, including as a result of disease outbreak, war, conflict or other political instability, or geopolitical risks, could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets, including disruptions caused by pandemic, war, conflict or other political instability, including Russia's invasion of Ukraine and resulting sanctions against Russia or conflict in the Middle East. Adverse macroeconomic conditions, and perceptions or expectations about current or future conditions, such as inflation, slowing growth, rising interest rates, rising unemployment and recession, could negatively affect our business and financial condition. Additionally, global events, including war, conflict, political instability or other adverse economic conditions have and may in the future cause governments to divert spending away from healthcare, negatively impacting the marketability of our products.

Any severe or prolonged economic downturn could create a variety of risks to our business, including weakened demand for our medicines, and negatively impacting our ability to raise additional capital or financing when needed on favorable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Additionally, geopolitical tensions could adversely impact our business and our commercial plans. For instance, restrictions by the U.S. government on the export of mRNA technology or our products to certain markets, or restrictions on the establishment of manufacturing in certain foreign jurisdictions, may prevent us from seeking commercial growth opportunities in a manner that harms our competitive position.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. Recently, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm. Any employment-related claim could negatively affect our business.

Ineffective internal controls could adversely impact our business and operating results.

Our internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, failure or interruption of information technology systems, the circumvention or overriding of controls, or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, our business and operating results could be harmed and we could fail to meet our financial reporting obligations.

Changes in tax law could adversely affect our business and financial condition.

We are subject to evolving and complex tax laws in the jurisdictions in which we operate. The rules dealing with U.S. federal, state, local and non-U.S. income taxation are constantly under review by legislative and tax authorities. Changes to tax laws (which could apply retroactively) could adversely affect us and our stockholders. In recent years, such changes have been made and changes are likely to occur in the future, which could have a material adverse effect on our business, cash flow, financial condition and results of operations.

The increasing use of social media platforms presents risks and challenges.

Social media is increasingly being used to communicate about our research, product candidates, commercial products and the diseases our products and product candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This uncertainty creates risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may be unable to defend our business in the face of political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cyber Risk Management and Strategy

Our cybersecurity organization’s mission is to provide a targeted set of services, support and capabilities to reduce the risk of cyberattacks, rapidly detect and contain threats, and mitigate risks to critical data.

Recognizing the threat of security breaches and cyberattacks globally, we have developed a cybersecurity program, overseen by our Chief Information Security Officer (CISO) and Chief Information Officer (CIO), that is designed to protect patient trust, defend the Moderna brand, and reduce the risk and impact of cyber-attacks. Our cybersecurity program is informed by industry standards and includes periodic risk assessments and security testing supported by cybersecurity technologies, including third-party security solutions, vulnerability management, and monitoring tools, designed to monitor, identify, and manage risks from cyber threats. In addition, we have implemented employee security and awareness training.

Management has established a cyber incident response plan (CIRP) designed to assess, identify and manage risks from cybersecurity threats and enable prompt response in the event that a cybersecurity incident is detected. We have a process in place for notification to our leadership response team in the event of a significant cyber incident, and for escalation of these events to our Audit Committee and Board, as appropriate. To date, we have not experienced a cybersecurity incident that has had a material impact on our business strategy, results of operations, or financial condition.

We undergo several annual internal compliance audits and external reviews to evaluate our controls, including cybersecurity controls. In an effort to minimize third-party risk, we have established a process to assess the security practices of third-party suppliers and related risks, including through review of relevant supplier certifications and security and responses to standardized information gathering (SIG) questionnaires, as applicable and appropriate.

Governance Related to Cybersecurity Risks

Our Board of Directors oversees Moderna's overall risk management strategy. The Board exercises oversight of risks from cybersecurity threats primarily through its Audit Committee, which oversees our risk management processes for information security and technology risks. Our cybersecurity risk management processes are integrated into our overall risk management strategy, which is overseen by the Audit Committee. At least annually, the Audit Committee discusses our risk management program, including information security and technology risks and findings from any audits, with our internal audit staff.

The Audit Committee receives cyber-related updates from management, including our CISO at committee meetings. During meetings, our CISO updates the committee on Moderna's cybersecurity posture, potential threats and risk mitigation strategies, and the progress of the Company's cybersecurity initiatives, as appropriate. The Chair of the Audit Committee and management provide regular briefings on such matters to the full Board of Directors, as appropriate.

At the management level, our CISO is primarily responsible for leading our cybersecurity strategy for assessing and managing material risks from cybersecurity threats. Our current CISO has over 25 years of cybersecurity experience across a wide array of industries, most recently serving in leadership positions at two different public companies and previous roles of increasing responsibility at multinational technology companies. Our CISO reports directly to our CIO, who is a member of our Executive Committee and reports to our Chief Executive Officer.

We have built a cybersecurity leadership team designed to align with key services, with a separate lead overseeing each service offering, all reporting to the CISO. We also maintain relationships with law enforcement and industry groups to support our cybersecurity intelligence and risk management efforts.

Item 2. Properties

We have two main campuses in Massachusetts. During the third quarter of 2023, we commenced a lease for a property in Cambridge, Massachusetts. This building, spanning approximately 462,000 square feet, is designated as our new Moderna Science Center (MSC). The MSC will accommodate a combination of scientific and office spaces, including our principal executive offices. The lease has a term of 15 years, with options for us to extend the lease for up to two additional seven-year terms. We expect to begin a phased move-in process starting in early 2024. Additionally, we occupy a multi-building campus at Technology Square in Cambridge, Massachusetts, consisting of a mix of offices and research laboratory space, totaling approximately 292,000 square feet. The lease will expire in early 2025. The Cambridge campus is the location of our corporate headquarters, platform, drug discovery and clinical development.

The Moderna Technology Center (MTC) is located in Norwood, Massachusetts and is primarily comprised of three buildings (MTC South, MTC North and MTC East). The MTC campus is approximately 686,000 square feet which includes lab and office space, directly supporting our manufacturing capabilities and commercial and clinical activities. The MTC campus is leased through 2042 and we have the option to extend it for three additional five-year terms.

In the second quarter of 2023, we acquired a newly constructed biomanufacturing facility, encompassing 140,000 square feet, in Marlborough, Massachusetts. This facility is undergoing enhancements, including the addition of 60,000 square feet to the existing structure. Upon completion, the facility will feature office and mRNA manufacturing areas, including a full manufacturing clean room, quality control laboratories, a just-in-time satellite warehouse, and additional office spaces. We expect the facility to be operational in 2025. This new site is strategically intended to support our INT program.

We also own and lease various parcels of land, office and lab spaces across the globe for our business operations.

Item 3. Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business, including the

intellectual property litigation described below. Most of the issues raised by these claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these and other legal proceedings we face, see Part I, Item 1A, "Risk Factors," including the discussion under the headings entitled "Risks related to our intellectual property" and "Risks related to the manufacturing of our commercial products and product candidates."

The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We describe below those legal matters for which a material loss is either (i) possible but not probable, and/or (ii) not reasonably estimable at this time.

Pfizer/BioNTech Patent Litigation

In August 2022, we filed a lawsuit in the U.S. District Court for the District of Massachusetts against Pfizer Inc. (Pfizer) and BioNTech SE, BioNTech Manufacturing GmbH and BioNTech US Inc. (collectively, BioNTech), asserting infringement of certain U.S. patents concerning our mRNA platform technology and disease-specific vaccine designs in Pfizer and BioNTech's manufacture and sale of their mRNA COVID-19 vaccines. The complaint seeks a judgment of infringement of the asserted patents and monetary damages.

Also in August 2022, we initiated patent infringement proceedings in Germany (in the Dusseldorf Regional Court), the Netherlands (in the District Court of The Hague) and the UK (in the High Court of Justice of England & Wales) against Pfizer, BioNTech and related entities with respect to certain European patents that also concern our mRNA platform technology and disease-specific vaccine designs, including coronaviruses. In May 2023, we initiated patent infringement proceedings in Ireland (in the High Court) and Belgium (Brussels Business Court) against Pfizer, BioNTech and related entities with respect to the same European patents. As in the U.S. action, we seek a judgment of infringement of the asserted patents and monetary damages.

Pfizer Inc. and BioNTech SE have also filed an action seeking revocation of certain Moderna patents in the UK. In addition, the Moderna patents being asserted in the European actions are subject to notices of opposition, including by Pfizer and BioNTech SE and others. These actions seek to revoke the patents, which have been filed at the European Patent Office.

Proceedings Related to Patents Owned by Arbutus

In February 2022, Arbutus Biopharma Corporation (Arbutus) and Genevant Sciences GmbH (Genevant) filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our COVID-19 vaccine willfully infringes certain U.S. patents concerning lipid nanoparticles. The complaint seeks a judgment of infringement of the asserted patents and monetary damages, but does not seek to prevent or stop the marketing or sales of our COVID-19 vaccines.

Proceedings Related to Patents Owned by Alnylam

In March 2022 and July 2022, Alnylam Pharmaceuticals, Inc. (Alnylam) filed two complaints against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our COVID-19 vaccine infringes certain U.S. patents concerning cationic lipids. On August 25, 2023, the Court entered a Final Judgment of non-infringement of all asserted patents in these lawsuits. Alnylam has appealed this judgment to the Federal Circuit Court of Appeals. In May 2023, Alnylam filed a third complaint against us in the U.S. District Court for the District of Delaware asserting three additional U.S. patents concerning cationic lipids. The complaints seek judgments of infringement of the asserted patents and monetary damages, but do not seek to prevent or stop the marketing or sales of our COVID-19 vaccines.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Our Common Stock

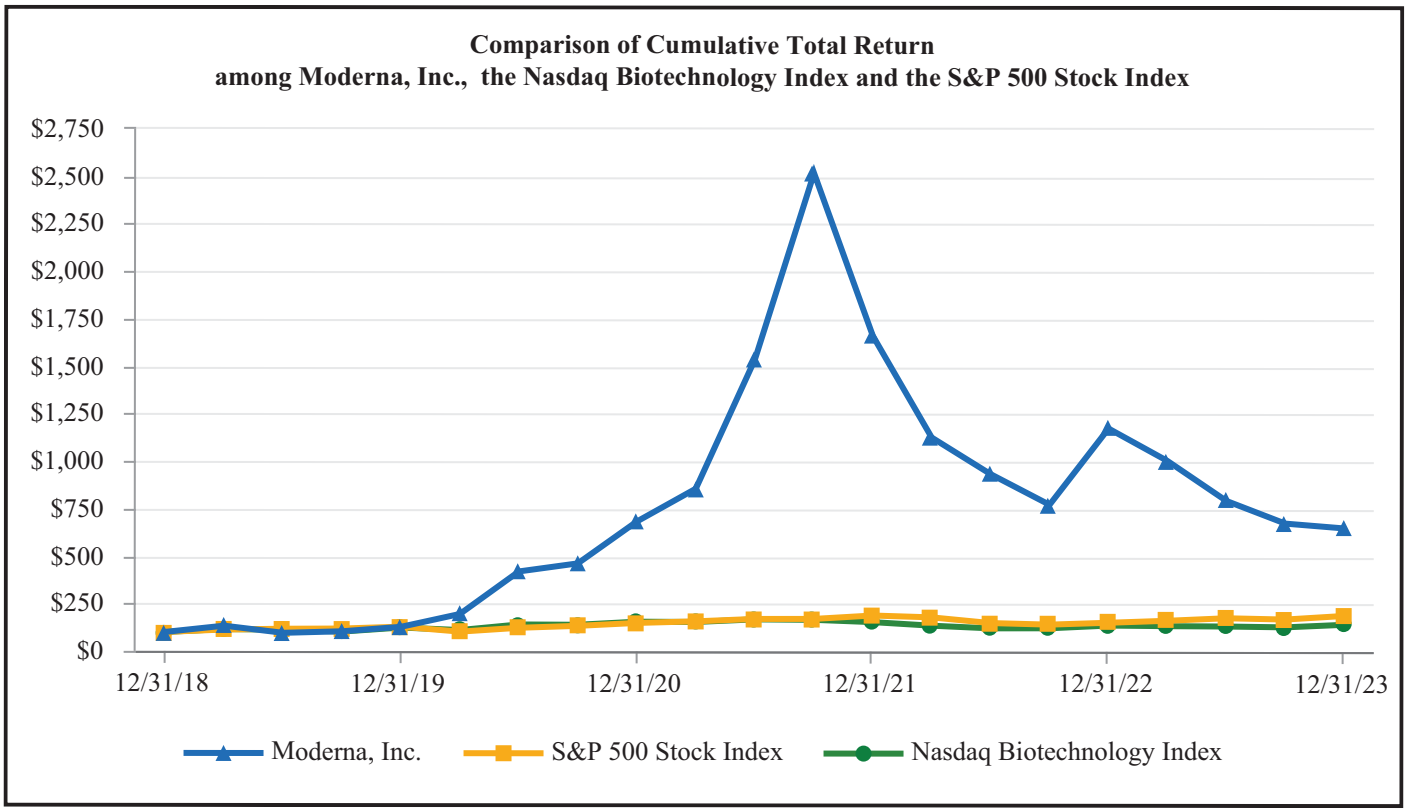
Our common stock trades on the Nasdaq Global Select Market under the symbol “MRNA”.

Stock Performance Graph

The following performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of the Exchange Act or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any filing of Moderna, Inc. under the Securities Act or the Exchange Act.

The following graph illustrates a comparison for the five years ended December 31, 2023 of the cumulative total return for our common stock, the Nasdaq Biotechnology Index, and the Standard & Poor’s 500 Stock Index (the S&P 500) each of which assumes an initial investment of $100 and reinvestment of all dividends. Such returns are based on historical results and are not intended to suggest future performance.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



Stockholders

We had approximately 75 stockholders of record as of February 16, 2024. Because many of our outstanding shares are held in accounts with brokers and other institutions, the number of beneficial owners is significantly greater than the number of record holders. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated herein by reference. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

On August 1, 2022, our Board of Directors authorized a share repurchase program for our common stock of up to $3.0 billion, with no expiration date. During the three months ended December 31, 2023, there were no shares repurchased. As of December 31, 2023, $1.7 billion of our Board of Directors' authorization for repurchases of our common stock remains outstanding, with no expiration date.

Refer to Note 12 to consolidated financial statements for information regarding our share repurchase programs.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in "Part I, Item 1A - Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company advancing a new class of medicines made of messenger RNA (mRNA). mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases, independently and with our strategic collaborators.

Since our founding in 2010, we have transformed from a research-stage company advancing programs in the field of mRNA to a commercial enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio and integrated manufacturing capabilities that allow for rapid clinical and commercial production at scale. We have a diverse and extensive development pipeline of 42 development candidates across our 45 development programs, of which 40 are in clinical studies currently.

Our COVID-19 vaccine is our first commercial product and is marketed, where approved, under the name Spikevax®. Our original vaccine, mRNA-1273, targeted the SARS-CoV-2 ancestral strain, and we have leveraged our mRNA platform to rapidly adapt our vaccine to emerging SARS-CoV-2 strains to provide protection as the virus evolves and regulatory guidance is updated.

2023 Business Highlights

On September 11, 2023, we received approval of the supplemental Biologics License Application from the U.S. Food and Drug Administration (FDA) for our updated COVID-19 vaccine, which targets the Omicron XBB.1.5 sublineage of SARS-CoV-2 (mRNA-1273.815), for individuals 12 years and older. The FDA also issued an Emergency Use Authorization for mRNA-1273.815 for children aged 6 months to 11 years old. We subsequently received authorization from regulatory authorities around the globe for mRNA-1273.815 and initiated the shipment of doses both in the U.S. and internationally.

For the year ended December 31, 2023, we recognized net product sales of $6.7 billion from sales of our COVID-19 vaccines, compared to $18.4 billion and $17.7 billion for the years ended December 31, 2022 and 2021, respectively.

In January 2023, we announced positive data from the interim analysis of our pivotal ConquerRSV study of our vaccine candidate against respiratory syncytial virus (RSV) (mRNA-1345). In the study, mRNA-1345 met primary efficacy endpoints, demonstrating vaccine efficacy of 83.7% against RSV lower respiratory tract disease in older adults. We have filed for a Biologics License Application to the FDA for our RSV vaccine for adults aged 60 years or older, and used a Priority Review Voucher to accelerate review. We have also submitted marketing authorization applications for the vaccine for adults aged 60 years or older to medical authorities in several countries beyond the U.S. We have initiated the manufacturing of mRNA-1345 and are preparing for a marketing launch in 2024, subject to approval.

During the third quarter of 2023, we embarked on a strategic initiative to optimize the cost structure of our COVID-19 business, with a focus on resizing our manufacturing cost structure. The launch of this initiative was prompted by the completion of our long-range planning within the third quarter of 2023, which incorporated revised forecasts of vaccination rates. These projections accounted for the market's transition from COVID-19 pandemic conditions towards an endemic seasonal market. Consequently, this strategic shift resulted in charges of $1.4 billion for the quarter. In the fourth quarter of 2023, we incurred additional charges of $169 million related to this initiative. Despite the immediate impact to our financial statements, we believe this strategic initiative will enhance the efficiency of our manufacturing operations and equip us with the agility to better adjust our scale according to future market demands.

Program Developments

As of December 31, 2023, nine of our 45 development programs are in late-stage development, including seven programs in Phase 3 and two rare disease programs that are expected to enter pivotal studies in 2024.

Respiratory Vaccines

- *Respiratory syncytial virus (RSV) vaccine:* We have filed for regulatory approvals for our vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults ages 60 years or older (mRNA-1345). We expect regulatory approvals beginning in the first half of 2024. We anticipate entering the RSV market with a strong competitive profile as the only pre-filled syringe product available at the time of launch, along with robust efficacy data, a well-established safety and tolerability profile, and widespread consumer awareness and demand established in 2023.

- *Next-generation COVID-19 vaccine:* Our next-generation COVID-19 vaccine candidate, which is designed to be refrigerator-stable (mRNA-1283), is currently in its pivotal Phase 3 study. We anticipate data from the study in the first half of 2024.

- *Seasonal flu vaccine:* Our seasonal flu vaccine candidate (mRNA-1010) demonstrated consistently acceptable safety and tolerability across three Phase 3 trials. In the most recent Phase 3 trial, mRNA-1010 met all immunogenicity endpoints, demonstrating higher titers compared to a currently licensed vaccine. mRNA-1010 has also shown higher or comparable titers compared to a currently licensed enhanced vaccine (Fluzone HD®) in a separate Phase 1/2 study. We are in discussions with regulators and intend to file in 2024.

- *Seasonal flu + COVID-19 vaccine:* The Phase 3 trial of our combination vaccine candidate against seasonal flu and COVID-19 (mRNA-1083) is fully enrolled. We anticipate data from the study in 2024.

Latent and Other Vaccines

- *Cytomegalovirus (CMV) vaccine:* The pivotal Phase 3 study of our CMV vaccine candidate (mRNA-1647) is fully enrolled and accruing cases, evaluating its efficacy, safety and immunogenicity in the prevention of primary infection in women of childbearing age. We anticipate potential efficacy data from the study in 2024.

Oncology Therapeutics

- *Individualized Neoantigen Therapy (INT):* We continue to demonstrate the potential clinical benefit of our INT program (mRNA-4157), which we are developing in collaboration with Merck. Two separate Phase 3 trials continue to enroll patients with resected high-risk (stage III/IV) melanoma and completely resected stage II, IIIA or IIIB non-small cell lung cancer. We and Merck plan to expand their clinical studies to additional tumor types in 2024.

  In December 2023, we announced results of a three-year analysis of our Phase 2b study evaluating INT in combination with KEYTRUDA®, Merck's anti-PD-1 therapy, in patients with resected high-risk melanoma. Compared to KEYTRUDA alone, this combination continued to show an improvement in recurrence-free survival, reducing the risk of recurrence or death by 49%, as well as in distant metastasis-free survival, reducing the risk of developing distant metastasis or death by 62%.

Rare Diseases

- *Propionic acidemia (PA) & methylmalonic acidemia (MMA):* We expect to advance our rare disease therapeutic programs for PA (mRNA-3927) and MMA (mRNA-3705) into pivotal studies in 2024.

Other Business Updates

In January 2023, we acquired OriCiro Genomics K.K., a Japan-based, privately held biotech company primarily focused on cell-free DNA synthesis and amplification technologies, for $86 million. With this acquisition, we obtained tools for cell-free synthesis and amplification of plasmid DNA, a key building block in mRNA manufacturing. OriCiro's technology strategically complements our manufacturing process, and we expect it will allow us to further accelerate our research and development efforts.

In February 2023, we entered into a strategic collaboration and license agreement with Life Edit Therapeutics Inc. (Life Edit) to collaborate on the discovery and development of *in vivo* mRNA gene editing therapies. The partnership will combine Life Edit's suite of proprietary gene editing technologies, including base editing, with our mRNA platform to advance *in vivo* gene editing therapies against a select set of therapeutic targets.

In March 2023, we entered into a strategic collaboration and license agreement with Generation Bio Co. (GBIO). The collaboration aims to expand the application of each company's platform by developing novel nucleic acid therapeutics, including those capable of reaching immune cells, to accelerate our respective pipelines of non-viral genetic medicines. Under the agreement, we have the option to license GBIO's proprietary cell-targeted lipid nanoparticle (ctLNP) and closed-ended DNA (ceDNA) technology for two immune cell programs and two liver programs, with an additional option for either a third immune cell or liver program.

In September 2023, we announced a strategic research and development collaboration agreement with Immatics, a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies. Upon effectiveness of the agreement in October 2023, we made an upfront payment of $120 million to Immatics. This collaboration between Moderna and Immatics centers on combining mRNA technology and T-cell receptor (TCR) platforms to develop cancer therapies, focusing on in vivo expression of TCR bispecifics (TCER®), creation of mRNA-based cancer vaccine utilizing extensive tumor data, and enhancing TCR-T cell therapy through combined preclinical and clinical studies.

Financial Operations Overview

Revenue

Net product sales

Net product sales by customer geographic location were as follows for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
United States	$ 1,720	$ 4,405	$ 5,393
Europe	1,353	6,732	6,834
Rest of world	3,598	7,298	5,448
Total	$ 6,671	$ 18,435	$ 17,675

In the third quarter of 2023, we commenced sales of our COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and organizations. In the U.S., our COVID-19 vaccine is now sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions. Please refer to Note 3 to our consolidated financial statements.

The following table summarizes product sales provision for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
Gross product sales	$ 8,203	$ 18,435	$ 17,675
Product sales provision:			
Wholesaler chargebacks, discounts and fees	(976)	—	—
Returns and other fees	(556)	—	—
Total product sales provision	$ (1,532)	$ —	$ —
Net product sales	$ 6,671	$ 18,435	$ 17,675

As of December 31, 2023, our COVID-19 vaccine was our only commercial product authorized for use.

As of December 31, 2023, we had deferred revenue of $613 million associated with customer deposits received or billable under supply agreements for delivery of our COVID-19 vaccine primarily in 2024.

Our net product sales for the full year 2023 declined significantly as compared to the full year 2022, reflecting the ongoing shift of the COVID-19 vaccine market toward a seasonal commercial market. In addition, we experienced greater seasonality for sales, with greater demand in the fall/winter seasons in each hemisphere as countries seek to provide booster vaccinations to their populations. For 2024, we expect the progression toward a seasonal commercial market to persist, resulting in further projected reductions in net product sales for our COVID-19 vaccine relative to 2023.

Other revenue

Other than net product sales, our revenue has been primarily derived from government-sponsored and private organizations including the Biomedical Advanced Research and Development Authority (BARDA), the Defense Advanced Research Projects Agency (DARPA) and the Bill & Melinda Gates Foundation and from strategic alliances with Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex) and others to discover, develop, and commercialize potential mRNA medicines.

The following table summarizes other revenue for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
Grant revenue	$ 94	$ 388	$ 735
Collaboration revenue	83	440	61
Total other revenue	$ 177	$ 828	$ 796

Cost of sales

Cost of sales includes raw materials, personnel and facility and other costs associated with manufacturing our commercial products. These costs include production materials, production costs at our manufacturing facilities, third-party manufacturing costs, and final formulation and packaging costs. Cost of sales also includes shipping costs, indirect overhead costs associated with our product sales during the period, third-party royalties on net sales of our products, and charges for inventory valuation, excess and obsolete inventory and losses on firm purchase commitments.

Research and development expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs.

Research and development expenses represent costs incurred by us for the following:

- cost to develop our platform;
- discovery efforts leading to development candidates;
- preclinical, nonclinical, and clinical development costs for our programs;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs related to our drug discovery efforts and clinical trials.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations (CROs), that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- expenses associated with developing manufacturing, modification of formulation or design of a product or process, advancing the design to meet specific functional and economic requirements for manufacture and obtaining materials for preclinical studies, clinical trials and pre-launch inventory from internal and third-party contract manufacturing organizations (CMOs);
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process;
- upfront fees and milestones paid to third-parties for licenses and technologies that had not reached technological feasibility and did not have an alternative future use; and
- facilities, depreciation, and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are generally not recorded or maintained on a program- or modality-specific basis.

The following table reflects our research and development expenses, including direct program specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the years ended December 31, 2023, 2022, and 2021 (in millions):

	Years Ended December 31,		
	2023	2022	2021
Program expenses by modality:			
Infectious disease vaccines	$ 2,344	$ 1,734	$ 1,099
Cancer vaccines & therapeutics	70	14	47
Rare disease intracellular therapeutics	75	42	26
Intratumoral immuno-oncology	23	10	20
Inhaled pulmonary therapeutics	17	18	1
Systemic secreted and cell surface therapeutics	33	23	3
Total program-specific expenses by modality [(1)]	$ 2,562	$ 1,841	$ 1,196
Other research and development expenses:			
Discovery programs	$ 106	$ 69	$ 85
Platform research	254	169	125
Technical development and unallocated manufacturing expenses	821	464	275
Shared discovery and development expenses	945	658	242
Stock-based compensation	157	94	68
Total research and development expenses	$ 4,845	$ 3,295	$ 1,991

(1) Includes a total of 42 development candidates at December 31, 2023, 45 development candidates at December 31, 2022, and 37 development candidates at December 31, 2021. Program-specific expenses are reflected as of the beginning of the period in which the program was internally advanced to development or removed if development was ceased.

A *"modality"* refers to a group of programs with common product features and the associated combination of enabling mRNA technologies, delivery technologies, and manufacturing processes. The program-specific expenses by modality summarized in the table above include expenses we directly attribute to our programs, which consist primarily of external costs, such as fees paid to outside consultants, central laboratories, investigative sites, and CROs in connection with our preclinical studies and clinical trials, CMOs, and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables. Costs to acquire and manufacture pre-launch inventory, mRNA supply for preclinical studies and clinical trials are recognized and included in unallocated manufacturing expenses when incurred, and subsequently allocated to program-specific manufacturing costs after completion of the program-specific production. The timing of allocating manufacturing costs to the specific program varies depending on the program development and production schedule. We generally do not allocate personnel-related costs, including stock-based compensation, costs associated with our general platform research, technical development, and other shared costs on a program-specific basis. These costs were therefore excluded from the summary of program-specific expenses by modality.

Discovery program expenses are costs associated with research activities for our programs in the preclinical discovery stage, and primarily consist of external costs for CROs and lab services, and allocated manufacturing cost of preclinical mRNA supply and consumables.

Platform research expenses are mainly costs to develop technical advances in mRNA science, delivery science, and manufacturing process design. These costs include personnel-related costs, computer equipment, facilities, preclinical mRNA supply and consumables, and other administrative costs to support our platform research.

Technology development and unallocated manufacturing expenses are primarily related to non-program-specific manufacturing process development and manufacturing costs.

Shared discovery and development expenses are research and development costs such as personnel-related costs and other costs, which are not otherwise included in development programs, discovery programs, platform research, technical development, certain collaborative and licensing arrangements, and unallocated manufacturing expenses, stock-based compensation, and other expenses.

Historically, we have made substantial investments in research and development activities, including development of our platform, mRNA technologies, and manufacturing technologies. We expense research and development costs as incurred and cannot reasonably estimate the nature, timing, and estimated costs required to complete the development of the development candidates and investigational medicines we are currently developing or may develop in the future.

Changes in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures. Continued research and development is central to the ongoing activities of our business. Investigational medicines in later stages of clinical development, such as our RSV vaccine, seasonal flu vaccine, CMV vaccine, new generations of COVID-19 vaccines, combination vaccines, and our INT program, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development costs to be substantial in the near term as our investigational medicines advance through development phases and as we identify and develop additional programs. We expect a modest reduction in research and development costs in 2024. There are numerous factors associated with the successful commercialization of any of our investigational medicines, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time due to the early stage of development of many of our investigational medicines. Moreover, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for executives, finance, legal, human resources, business development, commercial, marketing, and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs, and expenses associated with obtaining and maintaining intellectual property (IP). These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We anticipate selling, general and administrative expenses to decrease marginally in 2024 compared to 2023. This is due to the continued development of our programs and preparations for commercial activities both within and outside the United States. Our global expansion has already led to increased expenses, particularly as we build our regulatory, sales and marketing teams to support the commercialization of our COVID-19 vaccines and extend our global presence, with active subsidiaries in 19 countries as of December 31, 2023. Commercial and marketing efforts were significant contributors to our selling, general and administrative expenses in 2023, making up a substantial portion of these costs. If we obtain regulatory approval for additional investigational medicines without establishing third-party commercialization collaboration and manufacturing collaborations, we may incur further costs in developing these operational capacities. However, we anticipate selling, general and administrative expenses to decrease slightly compared to 2024, reflecting efficiencies gained from our established infrastructure and operations.

We have a broad IP portfolio covering our development and commercialization of mRNA vaccine and therapeutic programs, including those related to mRNA design, formulation, and manufacturing platform technologies. We regularly file patent applications to protect innovations arising from our research and development. We also hold trademarks and trademark applications in the United States and foreign jurisdictions. Costs to secure and defend our IP are expensed as incurred, and are classified as selling, general and administrative expenses.

Interest income

Interest income consists of interest generated from our investments in cash and cash equivalents, money market funds, and high-quality fixed income securities.

Other expense, net

Other expense, net consists of interest expense, gains (losses) from the sale of investments in marketable securities, gains (losses) related to changes in fair value of investments in equity securities, and other income and expense unrelated to our core operations. Interest expense is primarily derived from our finance leases related to our Moderna Technology Center and certain contract manufacturing service agreements.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, are reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Net product sales

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and organizations. The agreements and related amendments with these entities generally do not include variable consideration, such as discounts, rebates or returns. In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers.

We recognize net product sales when control of the product transfers to the customer, typically upon delivery. Net product sales in the U.S. are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions. These provisions are recorded based on contractual terms and our estimate of returns for product sold during the period, using the expected value method or the most likely amount method. Estimates are assessed each period and adjusted as required to revise information or actual experience. Please refer to Note 2 to our consolidated financial statements for further discussion and analysis of each significant category of product sales provisions and the accounting policy.

The application of our critical accounting policies necessitates substantial management judgment and estimation, particularly when determining the amount of variable consideration to recognize. The subjectivity of this process is heightened when assessing factors outside our direct control such as lack of pertinent historical data and limited third-party information. Among all variables, estimating returns presents the most significant judgment due to the broad range of potential outcomes and the current lack of return history with our customers. As we receive more historical data on our product returns, we will integrate this information to refine our estimates and enhance the precision of our financial projections. The actual results could differ from our estimates, and such differences could have a material impact to our financial statements.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined using first-in, first-out and average cost methods for different inventory components. We periodically review the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized through a charge to cost of sales. The process of determining whether inventory cost will be realizable requires significant judgment and estimates by management. If actual market conditions prove less favorable than projected by management, additional write-downs of inventory may be required. On a quarterly basis, we also assess whether we have any excess firm, non-cancelable, purchase commitment liabilities, resulting from our supply agreements with third-party vendors. The determination of net realizable value and firm purchase commitment liabilities requires significant judgment, including consideration of many factors, such as estimates of future product demand, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments and contractual minimums, among others. In 2023, the significant judgment included the write-down of raw materials due to our revised long-range plan, reflecting lower expected future demand for our COVID-19 vaccine. In prior years, this significant judgement was related to excess raw material purchase commitments from firm, non-cancelable purchase contracts with third-party vendors.

We maintain raw materials beyond our one-year forecasted production plan, which were classified as non-current and included in other non-current assets in our consolidated balance sheets. The classification and valuation of these materials involve significant

judgment and estimates. While we consider the assumptions used in estimating inventory write-downs to be reasonable, any significant future changes in these assumptions or shifts in future events and market conditions could lead to different estimates. Please refer to Note 7 to our consolidated financial statements for further discussion and analysis of these inventory related charges.

Income taxes

We account for income taxes based on an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. We determine our deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, we consider the scheduled reversal of deferred tax liabilities, uncertain tax positions, projected future taxable income and the effects of tax planning strategies in assessing the need for a valuation allowance.

During 2023, our assessment included consideration of a full-year pre-tax loss and a projected three-year cumulative loss as determined by our long-range financial planning process. This process indicated a significant decrease in expected sales of our COVID-19 vaccine as we transition to a seasonal market and substantial research and development expenses for ongoing Phase 3 clinical trials and the advancement of product candidates into later-stage development. These factors were considered as negative evidence in the realizability of our deferred tax assets. Furthermore, in assessing the need for a valuation allowance, we evaluated other sources of taxable income, such as taxable income in carryback years, available tax planning strategies, and the future reversals of taxable temporary differences. After a thorough evaluation of all available evidence, we determined it was more likely than not that we would not realize the majority of our deferred tax assets, leading us to maintain a valuation allowance of $2.2 billion against our deferred tax assets as of December 31, 2023. In the event that actual results differ from our estimates, or if future changes in estimates occur, the adjustments to the valuation allowance could materially impact our financial results. Such changes may result in significant increases or decreases to our tax provision in a period in which such estimates are changed, which in turn would affect net income or loss.

Recently issued accounting pronouncements

See Note 2 - Summary of Significant Accounting Policies, to the consolidated financial statements, under the caption “Recently Issued Accounting Standards Not Yet Adopted”.

Results of operations

A discussion regarding our results of operations for the year ended December 31, 2023 compared to 2022 is presented below. A discussion regarding our results of operations for the year ended December 31, 2022 compared to 2021 can be found under Part II - Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the Securities and Exchange Commission (SEC) on February 24, 2023.

The following table summarizes our consolidated statements of operations for the periods presented (in millions):

	Years Ended December 31,		Change 2023 vs. 2022	
	2023	2022	Change	%
Revenue:				
Net product sales	$ 6,671	$ 18,435	$ (11,764)	(64)%
Other revenue	177	828	(651)	(79)%
Total revenue	6,848	19,263	(12,415)	(64)%
Operating expenses:				
Cost of sales	4,693	5,416	(723)	(13)%
Research and development	4,845	3,295	1,550	47 %
Selling, general and administrative	1,549	1,132	417	37 %
Total operating expenses	11,087	9,843	1,244	13 %
(Loss) income from operations	(4,239)	9,420	(13,659)	(145)%
Interest income	421	200	221	111 %
Other expense, net	(124)	(45)	(79)	176 %
(Loss) income before income taxes	(3,942)	9,575	(13,517)	(141)%
Provision for income taxes	772	1,213	(441)	(36)%
Net (loss) income	$ (4,714)	$ 8,362	$ (13,076)	(156)%

Revenue

Total revenue decreased by $12.4 billion, or 64%, in 2023, primarily attributable to a significant reduction in net product sales of our COVID-19 vaccine. Net product sales decreased by $11.8 billion, or 64%, in 2023, mainly due to lower sales volume across all regions in 2023, reflecting the market's transition to a seasonal commercial market for COVID-19 vaccine. The decline was partially offset by a higher average selling price, particularly in the United States, where commercial market sales commenced in the third quarter of 2023. Other revenue decreased by $651 million, or 79%, in 2023, mainly due to a decrease in grant revenue under our agreement with BARDA for the development of our COVID-19 vaccine, and lower collaboration revenue following the recognition of Merck's $250 million participation payment related to our INT collaboration in 2022.

Operating expenses

Cost of sales

In the third quarter 2023, we launched a strategic initiative aimed at optimizing the cost structure of our COVID-19 business, with an emphasis on resizing our manufacturing cost structure. This initiative was triggered by the completion of our long-range planning within the third quarter of 2023, which incorporated revised forecasts of vaccination rates reflecting the market's transition from COVID-19 pandemic conditions to an endemic seasonal market. The initiative involved scaling down our capacity and commitments with our third-party CMOs, reevaluating our raw material inventory levels, and reducing our purchase commitments related to raw materials not anticipated to be consumed before expiration. As a result of this initiative, we incurred inventory write-downs of $903 million related to raw materials, and CMO wind down costs and cancellation fees of $513 million. Furthermore, as a continuation of this strategic initiative during the fourth quarter of 2023, we incurred $153 million in CMO wind down costs and $16 million in inventory write-downs. We believe that this strategic initiative will enhance the efficiency of our manufacturing operations and provide us with the flexibility to better scale according to future market needs.

Our cost of sales was $4.7 billion, or 70% of our net product sales, in 2023, including third-party royalties of $301 million, inventory write-downs of $2.2 billion, unutilized manufacturing capacity and wind down costs of $981 million, and losses on firm purchase

commitments and cancellation fees of $205 million. Our cost of sales was $5.4 billion, or 29% of our net product sales, in 2022, including third-party royalties of $1.1 billion, inventory write-downs of $1.3 billion, unutilized manufacturing capacity and wind down costs of $677 million, and losses on firm purchase commitments and cancellation fees of $725 million. These charges, other than royalties, were largely attributable to a shift in product demand to the latest variant-targeted COVID-19 vaccine and a decline in customer demand, which ultimately led to our strategic initiative implemented in the third quarter of 2023.

Cost of sales for 2023 decreased by $723 million, or 13%, compared to 2022. The decrease in cost of sales was primarily driven by lower sales volume, partially offset by an increase in inventory write-downs. Cost of sales as a percentage of net product sales for 2023 increased by 41 percentage points to 70% from 29% in 2022. The increase in cost of sales as a percentage of net product sales was mainly due to the strategic initiative described above, and other aforementioned charges (excluding royalties) over lower net product sales, driven by a decline in product demand and increased product seasonality. In light of our recent strategic initiative implemented in the third quarter of 2023, we expect a reduction in our cost of sales as a percentage of net product sales for the full year 2024, compared to the full year 2023.

Research and development expenses

Research and development expenses increased by $1.6 billion, or 47%, in 2023. The increase was primarily attributable to increases in clinical trial expenses of $411 million, clinical manufacturing expenses of $335 million, personnel-related costs of $286 million, and consulting and outside services of $267 million. The increase in 2023 was largely attributable to the late-stage clinical development associated with our RSV vaccine, CMV vaccine and combination vaccine against seasonal influenza and COVID-19, as well as our INT program. The increase in personnel-related costs was mainly driven by an increase in the number of employees supporting our increased research and development programs and activities.

We anticipate a modest reduction in research and development expenses in 2024 compared to the current levels of 2023, as we continue to advance the development of variant-specific and next-generation COVID-19 vaccine candidates and continue to develop our pipeline and advance our product candidates into later-stage development, in particular those in ongoing Phase 3 studies, including our RSV, CMV, seasonal flu and combination vaccine programs, as well as our INT program.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $417 million, or 37%, in 2023. The increase was mainly due to increases in personnel-related costs of $188 million, consulting and outside services of $148 million, and marketing expense of $118 million, partially offset by an endowment to the Moderna Charitable Foundation of $50 million contributed in 2022 that did not recur in 2023. The increase in 2023 was primarily driven by increased headcount and spend in digital, medical affairs and commercial functions to support our digital initiatives, marketed product and Company expansion.

We anticipate that selling, general and administrative expenses in 2024 will be slightly lower than the levels experienced in 2023. This reflects our ongoing commitment to efficiency as we expand our global commercial, regulatory, sales and marketing infrastructure. Moreover, it aligns with our strategic focus on advancing our program development and enhancing our overall business processes.

Interest income

Interest income generated from our investments in marketable securities increased by $221 million in 2023, mainly attributable to an overall higher interest rate environment, partially offset by lower average investment balances.

Other expense, net

The following table summarizes other expense, net for the periods presented (in millions):

	Years Ended December 31,		Change 2023 vs. 2022	
	2023	2022	Change	%
Loss on investments	$ (72)	$ (20)	$ (52)	260 %
Interest expense	(38)	(29)	(9)	31 %
Other (expense) income, net	(14)	4	(18)	(450)%
Total other expense, net	$ (124)	$ (45)	$ (79)	176 %

Total other expense, net increased by $79 million, or 176%, in 2023. The increase was primarily due to losses on equity investments and a net realized loss on available-for-sale debt securities as well as an increase in interest expense. Our interest expense is primarily

related to our finance leases. The increase in interest expense was driven by new finance leases that commenced in 2023. Please refer to Note 10 to our consolidated financial statements.

Provision for income taxes

Provision for income taxes decreased by $441 million, or 36%, in 2023, primarily due to a significant decrease in pre-tax income, partially offset by an increase in valuation allowance on deferred tax assets of $2.1 billion. Our effective tax rate for the year ended December 31, 2023 was (19.6)%, which is higher than the statutory rate. It is mainly driven by an increase in valuation allowances on deferred tax assets, partially offset by tax benefits from research and development credits and stock-based compensation. As a result of the significant reduction in pre-tax income and the valuation allowance, the 2023 effective tax rate is not comparable to the prior year. Please refer to Note 13 to our consolidated financial statements.

Liquidity and capital resources

The following table summarizes our cash, cash equivalents, investments and working capital for each period presented (in millions):

	December 31,	
	2023	2022
Financial assets:		
Cash and cash equivalents	$ 2,907	$ 3,205
Investments	5,697	6,697
Investments, non-current	4,677	8,318
Total	$ 13,281	$ 18,220
Working capital:		
Current assets	$ 10,325	$ 13,431
Current liabilities	3,015	4,923
Total	$ 7,310	$ 8,508

Our cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Our investments, consisting primarily of government and corporate debt securities, are stated at fair value. Cash, cash equivalents and investments as of December 31, 2023 decreased by $4.9 billion, or 27%, compared to December 31, 2022. For the year ended December 31, 2023, we had a net cash outflow from operations of $3.1 billion, repurchases of our common stock of $1.2 billion, and purchases of property, plant and equipment of $707 million.

Working capital, which is current assets less current liabilities, as of December 31, 2023 decreased by $1.2 billion, or 14%, compared to December 31, 2022, primarily due to a decrease in cash, cash equivalents and short-term investments of $1.3 billion, primarily to fund our operating activities and repurchases of our common stock, a decrease in inventory of $747 million, a decrease in prepaid and other current assets of $568 million, and a decrease in accounts receivable, net of $493 million. This was partially offset by a decrease in short-term deferred revenue of $1.5 billion, mainly driven by revenue recognized from deferred revenue in excess of customer deposits received.

Cash flow

The following table summarizes the primary sources and uses of cash for the periods presented (in millions):

	Years Ended December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (3,118)	$ 4,981
Investing activities	4,206	(5,176)
Financing activities	(1,377)	(3,448)
Net decrease in cash and cash equivalents	$ (289)	$ (3,643)

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits and accounts receivable, net related to our COVID-19 vaccine product sales, as well as certain government-sponsored and private organizations and strategic alliances. Our cash flows from operating activities are significantly affected by our use of cash for operating expenses and working capital to support the business. Beginning in the third quarter of 2020, we entered into supply agreements with the U.S. Government and foreign governments and organizations for the supply of our COVID-19 vaccine and received upfront deposits. In the third quarter of 2023, we commenced sales of our COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us. As of December 31, 2023, we had $613 million in deferred revenue related to customer deposits received or billable.

Net cash used by operating activities in 2023 was $3.1 billion and consisted of net loss of $4.7 billion and non-cash adjustments of $1.7 billion, plus a net change in assets and liabilities of $139 million. Non-cash items primarily included deferred income taxes of $828 million, depreciation and amortization of $621 million, and stock-based compensation of $305 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of $2.1 billion due to revenue recognized upon shipments of our COVID-19 vaccine, partially offset by a decrease in prepaid expenses and other assets of $1.0 billion, primarily driven by write-downs of long term inventory, decrease in income tax receivable due to receipt of tax refunds and decrease in pre-tax income, and reductions in vendor prepayments and down payments as well as a decrease in inventory of $747 million due to inventory write-downs.

Net operating cash flows decreased by $8.1 billion, or 163%, in 2023 compared to 2022, primarily attributable to a decrease in net income of $13.1 billion, a $1.3 billion change in accounts receivable due to lower product sales and timing of collection, and a $1.2 billion change in accounts payable and accrued liabilities driven by higher vendor spend and timing of payments. This was partially offset by a change in prepaid expenses and other assets of $2.7 billion primarily driven by inventory write-downs and reductions in vendor down payments, a change in deferred revenue of $2.1 billion due to less revenue recognized from deferred revenue in excess of customer deposits received, and a decrease in deferred income tax assets of $1.4 billion due to an increase in valuation allowance.

Investing activities

Our primary investing activities consist of purchases, sales, and maturities of our investments, capital expenditures for land, leasehold improvements, manufacturing, laboratory, computer equipment and software, and business development.

Net cash provided by investing activities in 2023 was $4.2 billion, which primarily included proceeds from maturities of marketable securities of $5.6 billion and proceeds from sales of marketable securities of $3.2 billion, partially offset by purchases of marketable securities of $3.8 billion, and purchases of property, plant and equipment of $707 million.

Net investing cash flows increased by $9.4 billion, or 181%, in 2023 compared to 2022, primarily due to a decrease in purchases of marketable securities of $7.7 billion and an increase in proceeds from maturities of marketable securities of $2.4 billion.

Financing activities

Our primary financing activities consist of repurchases of common stock, issuance of common stock related to our equity plans, and finance leases.

Net cash used in financing activities in 2023 was $1.4 billion, primarily from repurchases of common stock of $1.2 billion and changes in financing lease liabilities of $270 million, partially offset by net proceeds from the issuance of common stock in connection with the exercise of stock options and employee stock purchases under our equity plans of $46 million.

Net cash used in financing activities decreased by $2.1 billion, or 60%, in 2023 compared to 2022, mainly due to a decrease in repurchases of common stock.

Operation and funding requirements

Our principal sources of funding as of December 31, 2023 consisted of cash and cash equivalents, investments, and cash we may generate from operations. We generated net income of $8.4 billion and $12.2 billion for the years ended 2022 and 2021, respectively,

following the authorization of our first commercial product in December 2020. We also incurred a net loss of $4.7 billion for the year ended December 31, 2023. We have retained earnings of $13.6 billion as of December 31, 2023.

We have significant future capital requirements including expected operating expenses to conduct research and development activities, operate our organization, and meet capital expenditure needs. We anticipate maintaining substantial expenses across all areas of our ongoing activities, particularly as we continue research and development of our development candidates and clinical activities for our investigational medicines. This also extends to our manufacturing costs, including our arrangements with our supply and manufacturing partners. Our ongoing work on our RSV, seasonal flu and CMV vaccine candidates, individualized neoantigen therapy, COVID-19 vaccines, including development of any new vaccines against variants of SARS-CoV-2, combination vaccines, late-stage clinical development, and buildout of global commercial, regulatory, sales and marketing infrastructure and manufacturing facilities will require significant cash outflows in future periods, most of which may not be reimbursed or otherwise paid for by our partners or collaborators. In addition, we have substantial facility, lease and purchase obligations. We have also entered into certain collaboration agreements with third parties that include the funding of certain research and development activities and potential future milestone and royalty payments by us.

We believe that our cash, cash equivalents, and investments as of December 31, 2023, together with cash expected to be generated from product sales, will be sufficient to enable us to fund our projected operations and capital expenditures through at least the next 12 months from the issuance of the financial statements included in this Annual Report on Form 10-K. We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors, which may adversely affect our business. For example, we have experienced a decline in customer demand for our COVID-19 vaccine, reflecting the market's ongoing transition to a seasonal model in an endemic market in 2023. We foresee that our commitment to investing in our business for future product launches may lead to continued negative cash flows from operations in upcoming periods. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2023 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating leases	$ 1,133	$ 72	$ 134	$ 142	$ 785
Financing leases[1]	1,184	20	44	46	1,074
Purchase obligations[2]	2,103	1,002	685	272	144
Total contractual cash obligations	$ 4,420	$ 1,094	$ 863	$ 460	$ 2,003

(1) The amounts in the table include a total payment of $668 million associated with our MTC leases for the optional lease extension periods. For accounting purposes, a lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. Please refer to Note 10 to our consolidated financial statements.

(2) The amounts represent non-cancelable fixed payment obligations related to purchases of raw materials, contract manufacturing services, clinical services and other goods or services in the normal course of business. As of December 31, 2023, $79 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments.

We have agreements with certain vendors for various services, including services related to clinical operations, and support and contract manufacturing, which we are not contractually able to terminate for convenience. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly to reimburse them for their unrecoverable outlays incurred prior to cancellation. The exact amounts of such obligations are dependent on the timing of termination, and the exact terms of the relevant agreement and cannot be reasonably estimated. At December 31, 2023, we had cancelable open purchase orders of $3.0 billion in total under such agreements for our clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we

had a contractual commitment to pay at December 31, 2023, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the cancelable open purchase order amounts of $3.0 billion.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

As of December 31, 2023, we did not have any off-balance sheet arrangements that were material or reasonably likely to become material to our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of December 31, 2023 and 2022, we had cash, cash equivalents, restricted cash, and investments in marketable securities of $13.3 billion and $18.2 billion, respectively. Our investment portfolio comprises money market funds and marketable debt securities (including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities, and commercial paper), which are classified as available-for-sale securities. Our primary investment objectives are the preservation of capital and the maintenance of liquidity, and our investment policy defines allowable investments based on quality of the institutions and financial instruments designed to minimize risk exposure. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates.

Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term maturities and low risk profiles of our investments, we do not anticipate a significant exposure to interest rate risk. If market interest rates were to increase immediately and uniformly by one percentage point from levels at December 31, 2023, the net fair value of our marketable securities would decrease by approximately $83 million.

Foreign Currency Risk

We transact business in various foreign currencies and have international sales and expenses denominated in foreign currencies. Therefore, we are exposed to certain risks arising from both our business operations and economic conditions. For the year ended December 31, 2023, our revenue generating activities and operations continued to be primarily denominated in U.S. dollars. However, we maintained a significant exposure to foreign currency risk, particularly in the Euro, Japanese Yen and Swiss Franc markets, Our significant foreign currency revenue exposure was the equivalent of $1.4 billion in Japanese Yen and $518 million in Euros for 2023. As we pursue our international expansion strategy, our results of operations and cash flows remain subject to fluctuations in foreign currency exchange rates. To manage the exposure to foreign currency exchange rate fluctuations, we have implemented cash flow hedging and balance sheet hedging programs.

Cash Flow Hedging Activities

We mitigate the foreign exchange risk arising from the fluctuations in foreign currency denominated product sales in Euro and Japanese Yen through a foreign currency cash flow hedging program, using forward contracts and foreign currency options that do not exceed 15 months in duration. We hedge these cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash flows on hedged transactions. The derivative assets or liabilities associated with our hedging activities are recorded at fair value in prepaid expenses and other current assets or other current liabilities, respectively, in our consolidated balance sheets. The gains or losses resulting from changes in the fair value of these hedges are initially recorded as a component of accumulated other comprehensive (loss) income (AOCI) in stockholders' equity and subsequently reclassified to product sales in the period during which the hedged transaction affects earnings. In the event the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, within the defined hedge period, we reclassify the gains or losses on the related cash flow hedge from AOCI to other expense, net, in our consolidated statements of operations. We evaluate hedge effectiveness at the inception of the hedge prospectively, and on an on-going basis both retrospectively and prospectively. If we do not elect hedge accounting, or the contract does not qualify for hedge accounting treatment, the changes in fair value from period to period are recorded as a component of other expense, net, in our consolidated statements of operations. We had no outstanding foreign currency forward contracts or foreign currency options as of December 31, 2023. Foreign currency hedging activities were immaterial during 2023.

Balance Sheet Hedging Activities

We enter into foreign currency forward contracts to hedge fluctuations associated with foreign currency denominated monetary assets and liabilities, primarily cash, accounts receivable, accounts payable and lease liabilities in Euro, Swiss Franc and Japanese Yen, that are not designated for hedge accounting treatment. Therefore, these forward contracts are accounted for as derivatives whereby the fair value of the contracts are reported as prepaid expenses and other current assets or other current liabilities in our consolidated balance sheets, and gains and losses resulting from changes in the fair value are recorded as a component of other expense, net, in our consolidated statements of operations. The gains and losses on these foreign currency forward contracts generally offset the gains and losses in the underlying foreign currency denominated assets and liabilities, which are also recorded to other expense, net, in our consolidated statements of operations. As of December 31, 2023, our outstanding balance sheet hedging derivatives, carried at fair value, had maturities of less than three months.

We enter into these foreign exchange contracts to hedge our forecasted revenue and monetary assets and liabilities denominated in foreign currency in the normal course of business and accordingly, they are not speculative in nature. We believe the counterparties to

our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. As of December 31, 2023, a hypothetical adverse movement of 10 percent in foreign currency exchange rates compared to the U.S. dollars across all maturities would have resulted in potential declines in the fair value on our foreign currency forward contracts used in balance sheet hedging of approximately $23 million. We expect that any increase or decrease in the fair value of the portfolio would be substantially offset by increases or decreases in the underlying exposures being hedged.

Item 8. Financial Statements and Supplementary Data

MODERNA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	103
Consolidated Balance Sheets as of December 31, 2023 and 2022	105
Consolidated Statements of Operations for the years ended December 31, 2023, 2022, and 2021	106
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2023, 2022, and 2021	107
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2023, 2022, and 2021	108
Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022, and 2021	110
Notes to Consolidated Financial Statements	111

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Moderna, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Moderna, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 23, 2024, expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Reserves for returns on product revenue

Description of the Matter	During the year ended December 31, 2023, the Company's net product revenues for Spikevax were $6.7 billion. As explained in Note 2 of the consolidated financial statements, revenue from product sales includes estimates of variable consideration for which reserves are established, including reserves for product returns. Auditing the Company's measurement of reserves for product returns under its contracts with wholesalers, distributors and retail customers (collectively, "Customers") was especially challenging because (1) it involves management assumptions about inventory remaining in the distribution channel as of the balance sheet date that could be subject to return in future periods and projected market demand, and (2) the Company has limited returns history on which to base its assumptions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to determine reserves for returns on product revenue. For example, we tested controls over management's review of the completeness and accuracy of the data used in the process and the assumptions about the amount of inventory in the distribution channel that could be subject to return in future periods.

To test the Company's reserves for returns on product revenue, our audit procedures included, among other procedures, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the assumptions used by management to estimate its reserves. To test management's assumptions, we inspected agreements with significant Customers to validate the rights of return, made inquiries of members of the commercial function regarding any changes to the terms and conditions of commercial contracts. We also examined credit memos issued during and after year end for unusual items or trends not consistent with the Company's analysis of product returns and performed revenue cutoff testing at period end to assess whether there were unusual trends that should have been considered in the Company analysis of product returns. In addition, we reviewed inventory on hand-reporting from significant Customers at the balance sheet date and subsequent to the balance sheet date and inspected vaccination data from third-party sources through the report date. We also performed sensitivity analyses over the Company's return rate to assess the effect of changes in assumptions.

Raw Material Inventory Write-downs

Description of the Matter

As of December 31, 2023, the Company had $0.4 billion of inventory. As disclosed in Note 2, inventory is recorded at the lower of cost or net realizable value. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise unsaleable items. For the year ended December 31, 2023, inventory write-downs were $2.2 billion, which included $903 million in raw material inventory write-downs resulting from the Company's long-range financial planning process in the third quarter of 2023.

Auditing management's estimates for raw material inventory write-downs involved especially subjective auditor judgment because the estimates rely on a number of factors that are affected by market and economic conditions outside the Company's control. In particular, raw material inventory write-downs are sensitive to significant assumptions, including the expected demand for the Company's products and the expiration dates of the raw materials.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's raw material inventory write-down process including management's review of the significant assumptions described above and controls over the completeness and accuracy of the information used to develop the estimates.

To test the Company's raw material inventory write-downs, our audit procedures included, among other procedures, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the assumptions used by management in its estimates. Our testing of the data used in the Company's estimates included the accuracy of the raw material expiration dates used, materials required in the Company's products, and any alternate uses. We evaluated the Company's forecast of future demand, including testing of the significant assumptions within its forecast, and evaluating the consistency of the forecast with that used by management for other purposes. We also performed sensitivity analyses to assess the impact of changes in significant assumptions to the raw material inventory write-downs and evaluated any contrary evidence identified.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

Boston, Massachusetts

February 23, 2024

MODERNA, INC.
CONSOLIDATED BALANCE SHEETS
(In millions, except per share data)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 2,907	$ 3,205
Investments	5,697	6,697
Accounts receivable, net	892	1,385
Inventory	202	949
Prepaid expenses and other current assets	627	1,195
Total current assets	10,325	13,431
Investments, non-current	4,677	8,318
Property, plant and equipment, net	1,945	2,018
Right-of-use assets, operating leases	713	121
Deferred tax assets	81	982
Other non-current assets	685	988
Total assets	$ 18,426	$ 25,858
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 520	$ 487
Accrued liabilities	1,798	2,101
Deferred revenue	568	2,038
Income taxes payable	63	48
Other current liabilities	66	249
Total current liabilities	3,015	4,923
Deferred revenue, non-current	83	673
Operating lease liabilities, non-current	643	92
Financing lease liabilities, non-current	575	912
Other non-current liabilities	256	135
Total liabilities	4,572	6,735
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001; 162 shares authorized as of December 31, 2023 and 2022; no shares issued or outstanding at December 31, 2023 and 2022	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of December 31, 2023 and 2022; 382 and 385 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	371	1,173
Accumulated other comprehensive loss	(123)	(370)
Retained earnings	13,606	18,320
Total stockholders' equity	13,854	19,123
Total liabilities and stockholders' equity	$ 18,426	$ 25,858

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Years Ended December 31,		
	2023	**2022**	**2021**
Revenue:			
Net product sales	$ 6,671	$ 18,435	$ 17,675
Other revenue	177	828	796
Total revenue	6,848	19,263	18,471
Operating expenses:			
Cost of sales	4,693	5,416	2,617
Research and development	4,845	3,295	1,991
Selling, general and administrative	1,549	1,132	567
Total operating expenses	11,087	9,843	5,175
(Loss) income from operations	(4,239)	9,420	13,296
Interest income	421	200	18
Other expense, net	(124)	(45)	(29)
(Loss) income before income taxes	(3,942)	9,575	13,285
Provision for income taxes	772	1,213	1,083
Net (loss) income	$ (4,714)	$ 8,362	$ 12,202
(Loss) earnings per share:			
Basic	$ (12.33)	$ 21.26	$ 30.31
Diluted	$ (12.33)	$ 20.12	$ 28.29
Weighted average common shares used in calculation of (loss) earnings per share:			
Basic	382	394	403
Diluted	382	416	431

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In millions)

	Years Ended December 31,		
	2023	**2022**	**2021**
Net (loss) income	$ (4,714)	$ 8,362	$ 12,202
Other comprehensive income (loss), net of tax:			
Available-for-sale securities:			
Unrealized gains (losses) on available-for-sale debt securities	210	(348)	(42)
Less: net realized losses (gains) on available-for-sale securities reclassified in net (loss) income	38	26	(1)
Net increase (decrease) from available-for-sale debt securities	248	(322)	(43)
Cash flow hedges:			
Unrealized gains on derivative instruments	—	130	74
Less: net realized losses (gains) on derivative instruments reclassified in net (loss) income	8	(154)	(58)
Net increase (decrease) from derivatives designated as hedging instruments	8	(24)	16
Pension and postretirement benefit plans:			
Pension and postretirement obligation adjustments	(9)	—	—
Total other comprehensive income (loss)	247	(346)	(27)
Comprehensive (loss) income	$ (4,467)	$ 8,016	$ 12,175

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In millions)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	399	$ —	$ 4,802	$ 3	$ (2,244)	$ 2,561
Exercise of options to purchase common stock	7	—	112	—	—	112
Issuance of common stock under employee stock purchase plan	—	—	12	—	—	12
Stock-based compensation	—	—	142	—	—	142
Other comprehensive loss, net of tax	—	—	—	(27)	—	(27)
Repurchase of common stock	(3)	—	(857)	—	—	(857)
Net income	—	—	—	—	12,202	12,202
Balance at December 31, 2021	403	$ —	$ 4,211	$ (24)	$ 9,958	$ 14,145

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	403	$ —	$ 4,211	$ (24)	$ 9,958	$ 14,145
Vesting of restricted common stock	1	—	—	—	—	—
Exercise of options to purchase common stock	4	—	50	—	—	50
Issuance of common stock under employee stock purchase plan	—	—	15	—	—	15
Stock-based compensation	—	—	226	—	—	226
Other comprehensive loss, net of tax	—	—	—	(346)	—	(346)
Repurchase of common stock	(23)	—	(3,329)	—	—	(3,329)
Net income	—	—	—	—	8,362	8,362
Balance at December 31, 2022	385	$ —	$ 1,173	$ (370)	$ 18,320	$ 19,123

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	385	$ —	$ 1,173	$ (370)	$ 18,320	$ 19,123
Vesting of restricted common stock	1	—	—	—	—	—
Exercise of options to purchase common stock	4	—	25	—	—	25
Issuance of common stock under employee stock purchase plan	—	—	21	—	—	21
Stock-based compensation	—	—	305	—	—	305
Other comprehensive income, net of tax	—	—	—	247	—	247
Repurchase of common stock, including excise tax	(8)	—	(1,153)	—	—	(1,153)
Net loss	—	—	—	—	(4,714)	(4,714)
Balance at December 31, 2023	382	$ —	$ 371	$ (123)	$ 13,606	$ 13,854

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

	Years Ended December 31,		
	2023	2022	2021
Operating activities			
Net (loss) income	$ (4,714)	$ 8,362	$ 12,202
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Stock-based compensation	305	226	142
Depreciation and amortization	621	348	232
Amortization/accretion of investments	(61)	31	54
Loss on equity investments, net	35	—	—
Deferred income taxes	828	(559)	(318)
Other non-cash items	7	28	—
Changes in assets and liabilities, net of acquisition of business:			
Accounts receivable, net	493	1,790	(1,784)
Prepaid expenses and other assets	974	(1,699)	(489)
Inventory	747	492	(1,394)
Right-of-use assets, operating leases	(605)	21	(58)
Accounts payable	13	240	204
Accrued liabilities	(340)	612	989
Deferred revenue	(2,060)	(4,157)	2,824
Income taxes payable	15	(828)	876
Operating lease liabilities	551	(14)	17
Other liabilities	73	88	123
Net cash (used in) provided by operating activities	(3,118)	4,981	13,620
Investing activities			
Purchases of marketable securities	(3,760)	(11,435)	(12,652)
Proceeds from maturities of marketable securities	5,575	3,151	1,338
Proceeds from sales of marketable securities	3,206	3,548	3,105
Purchases of property, plant and equipment	(707)	(400)	(284)
Acquisition of business, net of cash acquired	(85)	—	—
Investment in convertible notes and equity securities	(23)	(40)	(30)
Net cash provided by (used in) investing activities	4,206	(5,176)	(8,523)
Financing activities			
Proceeds from issuance of common stock through equity plans	46	65	124
Repurchase of common stock, including excise tax	(1,153)	(3,329)	(857)
Changes in financing lease liabilities	(270)	(184)	(140)
Net cash used in financing activities	(1,377)	(3,448)	(873)
Net (decrease) increase in cash, cash equivalents and restricted cash	(289)	(3,643)	4,224
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860	2,636
Cash, cash equivalents and restricted cash, end of year	$ 2,928	$ 3,217	$ 6,860
Supplemental cash flow information			
Cash (received) paid for income taxes	$ (357)	$ 2,729	$ 480
Cash paid for interest	$ 39	$ 25	$ 14
Non-cash investing and financing activities			
Purchases of property, plant and equipment included in accounts payable and accrued liabilities	$ 130	$ 72	$ 111

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of the Business

Moderna, Inc. (collectively, with its consolidated subsidiaries, any of Moderna, we, us, our or the Company) is a biotechnology company advancing a new class of medicines made of messenger RNA (mRNA). mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases, independently and with our strategic collaborators.

Our COVID-19 vaccine is our first commercial product and is marketed, where approved, under the name Spikevax®. Our original vaccine, mRNA-1273, targeted the SARS-CoV-2 ancestral strain, and we have leveraged our mRNA platform to rapidly adapt our vaccine to emerging SARS-CoV-2 strains to provide protection as the virus evolves and regulatory guidance is updated.

We have a diverse and extensive development pipeline of 42 development candidates across our 45 development programs, of which 40 are in clinical studies currently.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

The consolidated financial statements include the Company and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Other revenue in the consolidated statements of operations comprises grant revenue and collaboration revenue that were previously presented as separate line items in our consolidated statements of operations in our 2022 Form 10-K. The associated prior period amounts in the consolidated financial statements, as well as in the notes thereto, have been reclassified to conform to the current presentation.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our consolidated financial statements and the accompanying notes. We base our estimates on historical experience and various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods that are not readily apparent from other sources. Changes in our estimates are recorded in the financial results of the period in which the new information becomes available. The actual results that we experience may differ materially from our estimates.

Segment Information

We have determined that our chief executive officer is the chief operating decision maker (CODM). The CODM reviews financial information presented on a consolidated basis. Resource allocation decisions are made by the CODM based on consolidated results. There are no segment managers who are held accountable by the CODM for operations, operating results, and planning for levels or components below the consolidated unit level. As such, we have concluded that we operate as one segment.

Revenue Recognition

To determine the appropriate amount of revenue to be recognized for arrangements that we determine are within the scope of ASC 606, we perform the following five steps (the five-step model): (i) identify the contract(s) with our customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as each performance obligation is satisfied.

Net Product Sales

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and organizations. The agreements and related amendments with these entities generally do not include variable consideration, such as discounts, rebates or returns. Certain of these agreements entitle us to upfront deposits for our COVID-19 vaccine supply, initially recorded as deferred revenue. In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to international governments and organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us.

We recognize net product sales when control of the product transfers to the customer, typically upon delivery. Payment terms generally range from 30 to 60 days, in line with customary practices in each country. Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions. These provisions are recorded based on contractual terms and our estimate of returns for product sold during the period, using the expected value method or the most likely amount method. We update our estimates quarterly and record necessary adjustments in the period when we identify the adjustments. Product sales, net of provisions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable when the uncertainty associated with the provisions is subsequently resolved. Shipping and handling activities are considered fulfillment activities and not a separate performance obligation. Taxes assessed by governmental authorities that are imposed on and collected from our product sales are excluded from net product sales.

Wholesaler chargebacks, discounts and fees

We contract with retailers, healthcare providers, and group purchasing organizations (GPO) to broaden our customer reach and offer contractual discounts. The chargeback represents the difference between the invoice price billed to the wholesaler and the negotiated price charged to the retailers, healthcare providers and GPO members. For distribution and related services, such as stocking and cold chain storage, we provide compensation to our wholesalers and distributors. We typically offer our customers invoice discounts on product sales for prompt payments and pre-orders. The estimation of these discounts and fees is based on contractual terms and our expectations regarding future customer payment behaviors. Wholesaler fees and invoice discounts are deducted from our gross product sales and accounts receivable at the time such product sales are recognized.

Product returns

We typically offer customers in the U.S. the right to return products, up to a certain limit as stipulated in our contracts. Estimated returns for our COVID-19 vaccine are determined considering available return rates for similar products, estimated levels of inventory in the distribution channel, and projected market demand. The estimated amount for product returns is presented within accrued liabilities on our consolidated balance sheets and is deducted from our gross product sales in the period the related product sales are recognized.

Other fees

Fees payable to third party payers and healthcare providers, along with fees to our direct customers that are settled via cash payments, including certain patient assistance programs, are recorded as accrued liabilities on our consolidated balance sheets.

Determining the amount of variable consideration to recognize necessitates substantial judgment, especially when assessing factors outside our direct control such as lack of pertinent historical data and limited third-party information. Among all variables, estimating returns presents the most significant judgment due to the broad range of potential outcomes and the current lack of return history with our customers. As we receive more historical data on our product returns, we will integrate this information to refine our estimates and enhance the precision of our financial projections. The actual results could differ from our estimates, and such differences could have a material impact to our financial statements.

Other Revenue

Other revenue consists primarily of grant revenue and collaboration revenue.

Grant revenue

We have contracts with government-sponsored and private organizations for research and development related activities that provide for payments for reimbursed costs, which may include overhead and general and administrative costs as well as a related profit margin. We recognize grant revenue from these contracts as we perform services under these arrangements when the funding is committed. Associated expenses are recognized when incurred as research and development expense. Grant revenue and related expenses are presented gross in the consolidated statements of operations as we have determined we are the primary obligor under the arrangements relative to the research and development services we perform as lead technical expert.

Collaboration Revenue

We have entered into strategic collaborations and other similar arrangements with third parties for research and other licenses, development and commercialization of certain products and product candidates. Such arrangements provide for various types of payments to us, including upfront fees, funding of research and development services and preclinical and clinical material, technical, development, regulatory, and commercial milestone payments, licensing fees, option exercise fees, and royalty and earnout payments on product sales. Such payments are often not commensurate with the timing of revenue recognition and therefore result in deferral of revenue recognition. We recognize revenue based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good or service to the customer.

Cash and Cash Equivalents

We consider all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash is composed of amounts held on deposit related to our lease arrangements and funds held in an escrow account related to a business acquisition in 2023. The funds are maintained in money market accounts and are recorded at fair value. Restricted cash is classified as either current or non-current based on the terms of the underlying arrangement and is included in either prepaid expenses and other current assets or other non-current assets in our consolidated balance sheets.

Cash, Cash Equivalents and Restricted Cash shown in the Consolidated Statements of Cash Flows

The following table provides a reconciliation of cash, cash equivalents and restricted cash in the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in millions):

	December 31,		
	2023	2022	2021
Cash and cash equivalents	$ 2,907	$ 3,205	$ 6,848
Restricted cash[(1)]	17	—	—
Restricted cash, non-current[(2)]	4	12	12
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 2,928	$ 3,217	$ 6,860

[(1)]Included in prepaid expenses and other current assets in the consolidated balance sheets.
[(2)]Included in other non-current assets in the consolidated balance sheets.

Investments

We invest our excess cash balances in marketable debt securities. We classify our investments in marketable debt securities as available-for-sale. We report our available-for-sale securities at fair value at each balance sheet date, and include any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific-identification method, and are included in other expense, net in our consolidated statements of operations. We classify our available-for-sale securities as current or non-current based on each instrument's underlying effective maturity date and for which we have the intent and ability to hold the investment for a

period of greater than 12 months. Available-for-sale securities with maturities of less than 12 months are classified as current and are included in investments in the consolidated balance sheets. Available-for-sale securities with maturities greater than 12 months for which we have the intent and ability to hold the investment for greater than 12 months are classified as non-current and are included in investments, non-current in the consolidated balance sheets.

We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit-related is recognized in other comprehensive income (loss), net of applicable taxes.

Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in other expense, net, in our consolidated statements of operations. Investments in equity securities without readily determinable fair values are recorded at cost minus impairment, if any, adjusted for changes resulting from observable price changes in orderly transactions for identical or similar securities. Such adjustments are recorded in other expense, net, in our consolidated statements of operations.

Accounts Receivable, net

Accounts receivable, net represent amounts due from customers less wholesalers chargebacks, discounts and fees (please refer to our "Revenue Recognition" policy within Note 2 for product sales provision) and allowance for expected credit losses. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. To estimate the allowance for credit losses, we determine the allowance based on ongoing credit evaluation, historical experience and the aging of such receivables, among other factors. There was no allowance for doubtful accounts at December 31, 2023 or 2022. Additionally, bad debt expenses were immaterial for the years ended December 31, 2023, 2022 and 2021.

Concentrations of Credit Risk

Financial instruments that subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, marketable debt securities, and accounts receivable, net. Our investment portfolio comprises money market funds and marketable debt securities, including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities and commercial paper. Our cash management and investment policy limits investment instruments to investment-grade securities with the objective to preserve capital and to maintain liquidity until the funds can be used in business operations. We invest in a variety of financial instruments and limit the amount of credit exposure with any individual financial institution. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. Our primary operating accounts significantly exceed the FDIC limits.

We are also subject to credit risk from our accounts receivable, net related to our net product sales and strategic alliances. We sell our products primarily to wholesalers and distributors and other governments and organizations. We do not require collateral or other security to support accounts receivable. To date, we have not experienced material losses with respect to the collection of our accounts receivable.

Significant Customers

Our accounts receivable, net are generally unsecured and are from customers in different countries. We generated revenue from product sales to wholesalers and distributors and other governments and organizations, and to a lesser extent, grants made by government-sponsored and private organizations, and collaboration revenue from our strategic alliances.

A significant portion of our revenue to date has been generated from the following entities that accounted for more than 10% of total revenue and accounts receivable for the periods presented:

	Percentage of Revenue Years Ended December 31,			Percentage of Accounts Receivable December 31,	
	2023	2022	2021	2023	2022
FFF Enterprises	*	*	*	39 %	*
European Commission	*	28 %	32 %	*	29 %
U.S. Government (excluding BARDA)	*	23 %	29 %	*	*
Takeda Pharmaceutical Company	*	10 %	*	*	*
Ministry of Health, Labor, and Welfare of Japan	21 %	*	*	*	30 %
UK Health Security Agency	*	*	*	35 %	11 %

** - Represents an amount of less than 10%*

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities, which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. ASC 820 *(Fair Value Measurement*) establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from our independent sources. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used to value the assets and liabilities:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; or
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Our cash equivalents and marketable debt securities are reported at fair value determined using Level 1 and Level 2 inputs (Note 6). The fair value of our foreign currency forward contracts is calculated using Level 2 inputs, which include currency spot rates, forward rates, interest rate curve and credit or non-performance risk. We do not have any non-financial assets or liabilities that should be recognized or disclosed at fair value on a recurring basis at December 31, 2023 and 2022.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined using first-in, first-out and average cost methods for different components of inventory. We periodically review the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized through a charge to cost of sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. We also assess whether we have any excess firm, non-cancelable, purchase commitment liabilities, resulting from our supply agreements with third-party vendors, on a quarterly basis. The determination of net realizable value and firm purchase commitment liabilities requires judgment, including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments and contractual minimums, among others. We hold raw materials beyond our one year forecasted production plan, which were classified as non-current and included in other non-current assets in our consolidated balance sheets.

Pre-launch Inventory

Costs relating to raw materials and production of inventory in preparation for product launch prior to regulatory approval are capitalized when future commercialization is considered probable, the future economic benefit is expected to be realized, and we believe that material uncertainties related to the ultimate regulatory approval have been significantly reduced. For pre-launch inventory that is capitalized, we consider a number of factors based on the information available at the time, including the product candidate's current status in the drug development and regulatory approval process, results from the related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential impediments to the approval process such as product safety or efficacy, historical experience, viability of commercialization and market trends. As of December 31, 2023, we did not have any capitalized pre-launch inventory on our consolidated balance sheets.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property, plant and equipment are described below:

	Estimated Useful Life
Land and land improvements	Not depreciated
Manufacturing and laboratory equipment	5 years
Leasehold improvements	Lesser of estimated useful life of improvement or remaining life of related lease
Computer equipment and software	3 to 5 years
Furniture and fixtures	5 years
Right-of-use asset, financing	Lease term

Construction in progress includes direct costs related to the construction of various property, plant and equipment, including leasehold improvements, and is stated at original cost. Once the asset is placed into service, these capitalized costs will be allocated to certain property, plant and equipment categories and will be depreciated over the estimated useful life of the underlying assets.

Acquisitions

We account for acquisitions either as business combinations or asset acquisitions, based on whether the set of assets acquired meets the definition of a business. When an acquisition is determined to be a business combination, we apply the acquisition method of accounting. This method requires that the assets acquired and liabilities assumed be recorded at their fair values as of the acquisition date on our consolidated balance sheets. Any excess of the consideration transferred over the fair value of the net identifiable assets acquired is recognized as goodwill. The process of determining the fair value of assets and liabilities involves significant estimates and assumptions. During the measurement period, which may extend up to one year from the acquisition date, we may record adjustments to these fair values. Any such adjustments are recorded with a corresponding change to goodwill. Transaction costs incurred in connection with business combinations are expensed as incurred.

On January 31, 2023, we completed a business combination by acquiring all outstanding shares of OriCiro Genomics K.K. for a cash consideration of $86 million. As a result of this acquisition, we recognized $52 million in goodwill and an intangible asset related to acquired technology valued at $48 million, which are included within other non-current assets in our consolidated balance sheets. This acquisition provided us with tools for cell-free synthesis and amplification of plasmid DNA, a key building block in mRNA

manufacturing. OriCiro's technology strategically complements our manufacturing process and further accelerates our research and development efforts.

Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired and is carried at cost. Goodwill is tested at least annually for impairment by assessing qualitative factors in determining whether it is more likely than not that the fair value of net assets is below their carrying amounts. To date, an impairment of goodwill has not been recorded.

The fair value of acquired intangible assets is determined by applying the income-based approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. To estimate the expected cash flows attributable to an intangible asset, it requires the use of Level 3 fair value measurements and inputs. Finite-lived intangible assets are amortized on a straight-line basis over their estimated useful lives.

Impairment of Long-Lived Assets, including Intangibles and Lease Right-of-Use Assets

We evaluate our long-lived assets, which consist of property, plant and equipment, intangibles and right-of-use assets to determine if facts and circumstances indicate that the carrying amount of assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the long-lived assets by comparing the projected future undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If such review indicates that such cash flows are not expected to be sufficient to recover the recorded value of the assets, the assets are written down to their estimated fair values based on the expected discounted future cash flows attributable to the assets or based on appraisals. Impairment expenses for the years ended December 31, 2023, 2022 and 2021 were immaterial.

Leases

Leases are classified at their commencement date, which is defined as the date on which the lessor makes the underlying asset available for use by the lessee, as either operating or finance leases based on the economic substance of the agreement. We recognize lease right-of-use assets and related liabilities in our consolidated balance sheets for both operating and finance leases. Lease liabilities are measured at the lease commencement date as the present value of the future lease payments using the interest rate implicit in the lease. If the rate implicit is not readily determinable, we will utilize our incremental borrowing rate as of the lease commencement date. Lease right-of-use assets are measured as the lease liability plus initial direct costs and prepaid lease payments less lease incentives. The lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised.

We recognize operating lease cost in operating expenses in our consolidated statements of operations, inclusive of rent escalation provisions and rent holidays, on a straight-line basis over the respective lease term. For our finance leases, we recognize depreciation expense associated with the leased asset acquired and recognize interest expense related to the portion of the financing in our consolidated statements of operations.

We do not separate non-lease components from lease components for all classes of underlying assets. We do not recognize right-of-use assets and lease liabilities for leases with a lease term of 12 months or less. Instead, these lease payments are recognized in the statements of operations on a straight-line basis over the lease term.

Collaboration Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808 (*Collaborative Arrangements*) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, we assess whether aspects of the arrangement between us and our collaboration partner are within the scope of other accounting literature. If we conclude that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606 *(Revenue from Contracts with Customers*). Please refer to our "Revenue Recognition" policy within Note 2 for additional discussion of revenue recognition under these types of arrangements. If we conclude that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, we recognize our allocation of the shared costs incurred with respect to the jointly conducted activities as a component of the related expense in the period incurred. Additionally, for any payments related to capital expenditures that are partially reimbursed by a collaboration partner, to the extent the underlying capital costs qualify for capitalization, any reimbursements received will offset the capitalized cost of the asset.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, overhead costs, contract services, and other outside costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier. Research and development costs also include costs and shared cost associated with third-party collaboration arrangements, including upfront fees and milestones paid to third-parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use.

Assets that are acquired or constructed for research and development activities and that have alternative future uses, in research and development projects or otherwise, are capitalized and depreciated over their useful lives. However, the costs of equipment or facilities that are acquired or constructed and intangibles that are purchased from others for a particular research and development project, and that have no alternative future uses and therefore no separate economic values, are considered research and development costs and expensed when incurred.

Advertising Costs

Costs associated with advertising are expensed as incurred and are included in selling, general and administrative expense in the consolidated statements of operations. Advertising expenses were $204 million in 2023, $121 million in 2022, and immaterial in 2021.

Stock-Based Compensation

We issue stock-based awards to employees and non-employees, generally in the form of stock options, restricted stock units (RSUs), and performance stock units (PSUs). We account for our stock-based compensation awards in accordance with ASC 718 *(Compensation—Stock Compensation)*. Most of our stock-based awards have been made to employees. We measure compensation cost for equity awards at their grant-date fair value and recognize compensation expense over the requisite service period, which is generally the vesting period, on a straight-line basis. The grant date fair value of stock options is estimated using the Black-Scholes option pricing model, which requires management to make assumptions with respect to the fair value of our common stock on the grant date, including the expected term of the award, the expected volatility of our stock, calculated based on a period of time generally commensurate with the expected term of the award, risk-free interest rates and expected dividend yields of our stock. We estimate the expected term of our stock options granted to employees and non-employees using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, and because significant changes in our business over the past few years have rendered historical experience less relevant. The expected volatility is based on a blended average of average historical stock volatilities of selected guideline companies over the expected term of the stock options, historical volatility of our stock price, and implied stock price volatility derived from the price of exchange traded options on our stock. Given the transformative changes in our business, we believe that a blended volatility rate is more indicative of future volatility than our historical volatility alone. We will continue to apply this process until a sufficient amount of historical information regarding the expected term and historical volatility of our own stock price becomes available, and until we believe that historical experience is relevant to our expectations for current grants. The grant date fair value of RSUs is estimated based on the fair value of our underlying common stock. For performance-based stock awards, we recognize stock-based compensation expense over the requisite service period using the accelerated attribution method when achievement is probable. We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. We made an accounting policy election to recognize forfeitures of stock-based awards as they occur.

Income Taxes

We account for income taxes based on an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided when the expected realization of deferred tax assets does not meet a "more likely than not" criterion. We periodically reassess the need for valuation allowances on our deferred tax assets, considering both positive and negative evidence to evaluate whether it is more likely than not that all or a portion of such assets will not be realized. We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to our tax provision in a period in which such estimates are changed, which in turn would affect net income or loss. We recognize tax benefits from uncertain tax positions if we believe the position is more likely than not to be sustained on examination by the taxing authorities based on the technical merits of the position. We make adjustments

to these tax reserves when facts and circumstances change, such as the closing of a tax audit or the refinement of an estimate. The provision for income taxes includes the effects of any reserves for uncertain tax positions, as well as the related net interest and penalties.

Earnings (Loss) per Share

We calculate diluted net earnings (loss) per share attributable to common stockholders by dividing net earnings (loss) by the weighted average number of common shares outstanding after giving consideration to the dilutive effect of restricted common stock and stock options that are outstanding during the period. For periods in which we have generated a net loss, the basic and diluted net loss per share attributable to common stockholders are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) and other comprehensive income (loss) for the period. Other comprehensive income (loss) consists of unrealized gains and losses on our investments and derivatives designated as hedging instruments. Total comprehensive income (loss) for all periods presented has been disclosed in the consolidated statements of comprehensive income (loss).

The components of accumulated other comprehensive loss for the years ended December 31, 2023 and 2022 were as follows (in millions):

	Unrealized (Loss) Gain on Available-for-Sale Securities	Net Unrealized Gain (Loss) on Derivatives Designated As Hedging Instruments	Pension and Postretirement Benefits	Total
Accumulated other comprehensive loss, balance at December 31, 2021	$ (40)	$ 16	$ —	$ (24)
Other comprehensive loss	(322)	(24)	—	(346)
Accumulated other comprehensive loss, balance at December 31, 2022	(362)	(8)	—	(370)
Other comprehensive income (loss)	248	8	(9)	247
Accumulated other comprehensive loss, balance at December 31, 2023	$ (114)	$ —	$ (9)	$ (123)

Share Repurchases

Shares of our common stock repurchased pursuant to our repurchase programs are retired. The purchase price of such repurchased shares of common stock is recorded as a reduction to additional paid-in-capital. If the balance in additional paid-in-capital is exhausted, the excess is recorded as a reduction to retained earnings.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Except as noted below, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* This ASU broadens the disclosure requirements by requiring disclosures of significant segment expenses that are regularly provided to the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss. The standard also requires entities to disclose, on an interim and annual basis, the amount and description, including the nature and type, of the other segment items. Additionally, entities are required to disclose the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. These enhanced disclosure obligations apply to entities that operate with one reportable segment as well. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. Early adoption is permitted. We are currently assessing the impact that this new accounting standard will have on our consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The standard requires entities to disclose federal, state, and foreign income taxes in their rate reconciliation tables

and elaborate on reconciling items that exceed a quantitative threshold. Additionally, it requires an annual disclosure of income taxes paid, net of refunds, categorized by jurisdiction based on a quantitative threshold. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted.

3. Net Product Sales

Net product sales by customer geographic location were as follows for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
United States	$ 1,720	$ 4,405	$ 5,393
Europe	1,353	6,732	6,834
Rest of world	3,598	7,298	5,448
Total	$ 6,671	$ 18,435	$ 17,675

As of December 31, 2023, 2022 and 2021, our COVID-19 vaccine was our only commercial product authorized for use.

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and organizations. The agreements and related amendments with these entities generally do not include variable consideration, such as discounts, rebates or returns. Certain of these agreements entitle us to upfront deposits for our COVID-19 vaccine supply, initially recorded as deferred revenue.

As of December 31, 2023 and 2022, we had deferred revenue of $613 million and $2.6 billion, respectively, related to customer deposits. We expect $554 million of our deferred revenue related to customer deposits as of December 31, 2023 to be realized in less than one year. Timing of product delivery and manufacturing, and receipt of marketing approval for the applicable COVID-19 vaccine will determine the period in which net product sales are recognized.

In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us.

Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions.

The following table summarizes product sales provision for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
Gross product sales	$ 8,203	$ 18,435	$ 17,675
Product sales provision:			
Wholesaler chargebacks, discounts and fees	(976)	—	—
Returns and other fees	(556)	—	—
Total product sales provision	$ (1,532)	$ —	$ —
Net product sales	$ 6,671	$ 18,435	$ 17,675

The following table summarizes the activities related to product sales provision recorded as accrued liabilities for the year ended December 31, 2023 (in millions):

	Returns and other fees
Balance at December 31, 2022	$ —
Provision related to sales made in current period	(556)
Balance at December 31, 2023	$ (556)

4. Other Revenue

The following table summarizes other revenue for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
Grant revenue	$ 94	$ 388	$ 735
Collaboration revenue	83	440	61
Total other revenue	$ 177	$ 828	$ 796

Grant Revenue

In April 2020, we entered into an agreement with Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), for an award of up to $483 million to accelerate development of mRNA-1273, our original vaccine candidate against COVID-19. The agreement has been subsequently amended to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials, adolescent clinical trials and pharmacovigilance studies. The maximum award from BARDA, inclusive of all amendments, was approximately $1.8 billion. All contract options have been exercised. As of December 31, 2023, the remaining available funding, net of revenue earned was $97 million.

The following table summarizes grant revenue for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
BARDA	$ 88	$ 372	$ 713
Other grant revenue	6	16	22
Total grant revenue	$ 94	$ 388	$ 735

Collaboration Revenue

We have entered into collaboration agreements with strategic collaborators to accelerate the discovery and advancement of potential mRNA medicines across therapeutic areas. As of December 31, 2023, 2022 and 2021, we had collaboration agreements with Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex), AstraZeneca plc (AstraZeneca) and others. Please refer to Note 5 to for further description of these collaboration agreements.

The following table summarizes our total consolidated net revenue from our strategic collaborators for the periods presented (in millions):

	Years Ended December 31,		
Collaboration Revenue by Strategic Collaborator:	2023	2022	2021
Vertex	$ 82	$ 48	$ 26
Merck	—	309	23
AstraZeneca	—	80	7
Other	1	3	5
Total collaboration revenue	$ 83	$ 440	$ 61

5. Collaboration Agreements

Merck – Personalized mRNA Cancer Vaccines (Individualized Neoantigen Therapy)

In June 2016, we entered into a Collaboration and License Agreement for the development and commercialization of personalized mRNA cancer vaccines (also known as individualized neoantigen therapy (INT)) with Merck, to develop and commercialize INTs for individual patients using our mRNA and formulation technology. This agreement was subsequently amended and restated in 2018 (INT Agreement). Our role in this strategic alliance involves identifying genetic mutations in a particular patient's tumor cells, synthesizing mRNA for these mutations, encapsulating the mRNA in one of our proprietary lipid nanoparticles (LNPs), and administering a unique mRNA INT to each patient. Each INT is designed to specifically activate the patient's immune system against her or his own cancer cells.

Pursuant to the INT Agreement, we received an upfront payment of $200 million from Merck and we were responsible for designing and researching INTs, providing manufacturing capacity and manufacturing INTs and conducting Phase 1 and Phase 2 clinical trials for INTs, alone and in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget. We concluded that the collaboration arrangement was governed by the revenue recognition standard ASC 606.

In September 2022, Merck exercised its option for INT, including mRNA-4157, pursuant to the terms of the agreement and in October 2022 paid us an option exercise fee of $250 million. Pursuant to the agreement, we and Merck have agreed to collaborate on further development and commercialization of INT, with costs and any profits or losses to be shared equally on a worldwide basis. We concluded that the collaboration arrangement under the Merck Participation Term is within the scope of ASC 808. For the years ended December 31, 2023 and 2022, we recognized expense of $184 million and $6 million, net of Merck's reimbursements, related to the INT collaboration under the Merck Participation Term. Additionally, the net cost recovery for capital expenditures during the same periods were $102 million and $3 million, respectively, which were applied to reduce the capitalized cost of the asset.

Vertex – Strategic Alliance in Cystic Fibrosis

2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement (Vertex Agreement), with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited, together, Vertex. The Vertex Agreement, which was amended in July 2019 (2019 Vertex Amendment), is aimed at the discovery and development of potential mRNA medicines for the treatment of cystic fibrosis (CF) by enabling cells in the lungs of people with CF to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) proteins. Pursuant to the Vertex Agreement, we lead discovery efforts during an initial research period, leveraging our platform technology and mRNA delivery expertise along with Vertex's scientific experience in CF biology and the functional understanding of CFTR. Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Subject to customary "back-up" supply rights granted to Vertex, we exclusively manufacture (or have manufactured) mRNA for preclinical, clinical and commercialization purposes. This collaboration arrangement is accounted for under ASC 606 and currently ongoing.

2020 Strategic Alliance in Cystic Fibrosis

In September 2020, we entered into a Strategic Collaboration and License Agreement with Vertex (Vertex 2020 Agreement). The Vertex 2020 Agreement was aimed at the discovery and development of potential medicines to treat CF by delivering gene-editing therapies to lung cells to facilitate production of functional CFTR proteins. The three-year research period of the Vertex 2020 Agreement was initially focus on the identification and optimization of novel LNPs and mRNAs that can deliver gene-editing therapies to cells in the lungs. Following the initial three-year period, Vertex was responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Vertex was also obligated to pay us for research services in connection with our performance of certain activities in accordance with a jointly agreed research plan. This collaboration was concluded and terminated in the fourth quarter of 2023 in accordance with the terms of the Vertex 2020 Agreement.

AstraZeneca – Strategic Alliances in Cardiovascular and Oncology

We entered into collaboration agreements with AstraZeneca in 2013 and 2016, aimed at developing mRNA medicines for treatments in cardiovascular, cardiometabolic diseases, and cancer. These agreements provided AstraZeneca with exclusive development and commercialization rights for specific programs, including the VEGF-A product AZD8601 and an immuno-oncology program for IL-12, with upfront payments to us totaling $240 million.

In the third quarter of 2022, AstraZeneca terminated our collaborations with them, including the development of VEGF-A and IL-12 programs, for which termination became effective on November 21, 2022. All rights to these two programs reverted to us. As a result of the termination, we recognized the remaining deferred revenue of $76 million as collaboration revenue in the period.

Immatics – Strategic Multi-Platform Collaboration to Develop Oncology Therapeutics

In September 2023, we entered into a strategic research and development collaboration agreement with Immatics, a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies. We will lead the clinical development and commercialization of cancer vaccines and TCER® therapeutics resulting from the collaboration. Immatics will be responsible for conducting the preclinical studies and a potential Phase 1 clinical trial investigating IMA203 TCR-T in combination with the PRAME mRNA vaccine to further enhance IMA203 T cell responses. Each party will retain full ownership of its investigational PRAME compound, and the parties will fund the clinical study on a cost sharing basis.

Upon effectiveness of the agreement in October 2023, we made an upfront payment of $120 million to Immatics. The payment was recognized as research and development expense in the same period. Immatics will also receive research funding and is eligible to receive development, regulatory, and commercial milestone payments. Immatics is also eligible to receive tiered royalties on global net sales of TCER® products and certain vaccine products that are commercialized under the agreement. Under the agreement, Immatics has an option to enter into a global profit and loss share arrangement for the most advanced TCER®.

In addition to the collaborative arrangements mentioned above, we have other collaborative and licensing arrangements that we do not consider to be individually significant to our business at this time. Pursuant to these agreements, we may be required to make upfront payments and payments upon achievement of various development, regulatory and commercial milestones, which in the aggregate could be significant. Future milestone payments, if any, will be reflected in our consolidated financial statements when the corresponding events become probable. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized.

6. Financial Instruments and Fair Value Measurements

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category at December 31, 2023 and 2022 (in millions):

	December 31, 2023						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 2,907	$ —	$ —	$ 2,907	$ 2,907	$ —	$ —
Available-for-sale:							
Certificates of deposit	27	—	—	27	—	27	—
U.S. treasury bills	807	—	—	807	—	807	—
U.S. treasury notes	4,407	3	(67)	4,343	—	2,664	1,679
Corporate debt securities	5,067	3	(81)	4,989	—	2,082	2,907
Government debt securities	211	—	(3)	208	—	117	91
Total	$ 13,426	$ 6	$ (151)	$ 13,281	$ 2,907	$ 5,697	$ 4,677

	December 31, 2022						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 3,205	$ —	$ —	$ 3,205	$ 3,205	$ —	$ —
Available-for-sale:							
Certificates of deposit	188	—	—	188	—	188	—
U.S. treasury bills	767	—	—	767	—	767	—
U.S. treasury notes	7,781	—	(229)	7,552	—	4,182	3,370
Corporate debt securities	6,595	—	(226)	6,369	—	1,560	4,809
Government debt securities	148	—	(9)	139	—	—	139
Total	$ 18,684	$ —	$ (464)	$ 18,220	$ 3,205	$ 6,697	$ 8,318

The amortized cost and estimated fair value of available-for-sale securities, by contractual maturity at December 31, 2023 and 2022 were as follows (in millions):

	December 31, 2023	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 5,751	$ 5,697
Due after one year through five years	4,768	4,677
Total	$ 10,519	$ 10,374

	December 31, 2022	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 6,792	$ 6,697
Due after one year through five years	8,687	8,318
Total	$ 15,479	$ 15,015

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. We did not record any impairment charges related to our available-for-sale securities during the years ended December 31, 2023, 2022, and 2021. We did not recognize any credit-related allowance to available-for-sale securities as of December 31, 2023 and 2022.

The following table summarizes the amount of gross unrealized losses and the estimated fair value for our available-for-sale securities in an unrealized loss position by length of time the securities have been in an unrealized loss position at December 31, 2023 and 2022 (in millions):

	Less than 12 Months		12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2023:						
U.S. treasury bills	$ —	$ 25	$ —	$ —	$ —	$ 25
U.S. treasury notes	(3)	774	(64)	2,983	(67)	3,757
Corporate debt securities	(1)	562	(79)	3,518	(80)	4,080
Government debt securities	—	8	(4)	143	(4)	151
Total	$ (4)	$ 1,369	$ (147)	$ 6,644	$ (151)	$ 8,013
As of December 31, 2022:						
U.S. treasury securities	$ —	$ 128	$ —	$ —	$ —	$ 128
U.S. treasury notes	(101)	3,956	(128)	3,541	(229)	7,497
Corporate debt securities	(138)	3,505	(88)	1,890	(226)	5,395
Government debt securities	(2)	46	(7)	93	(9)	139
Total	$ (241)	$ 7,635	$ (223)	$ 5,524	$ (464)	$ 13,159

At December 31, 2023 and 2022, we held 392 and 582 available-for-sale securities, respectively, out of our total investment portfolio that were in a continuous unrealized loss position. We neither intend to sell these investments nor conclude that we are more-likely-than-not that we will have to sell them before recovery of their carrying values. We also believe that we will be able to collect both principal and interest amounts due to us at maturity.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables summarize our financial assets measured at fair value on a recurring basis as of December 31, 2023 and 2022 (in millions):

	Fair value at December 31, 2023	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 1,572	$ 1,572	$ —
Certificates of deposit	27	—	27
U.S. treasury bills	1,246	—	1,246
U.S. treasury notes	4,343	—	4,343
Corporate debt securities	5,480	—	5,480
Government debt securities	208	—	208
Equity investments[(1)]	24	24	—
Derivative instruments	4	—	4
Total	$ 12,904	$ 1,596	$ 11,308
Liabilities:			
Derivative instruments	$ 9	$ —	$ 9

	Fair value at December 31, 2022	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 1,079	$ 1,079	$ —
Certificates of deposit	188	—	188
U.S. treasury bills	767	—	767
U.S. treasury notes	7,552	—	7,552
Corporate debt securities	6,369	—	6,369
Government debt securities	139	—	139
Derivative instruments	6	—	6
Total	$ 16,100	$ 1,079	$ 15,021
Liabilities:			
Derivative instruments	$ 32	$ —	$ 32

[(1)]Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in other expense net, in our consolidated statements of operations.

As of December 31, 2023 and 2022, we did not have non-financial assets or liabilities measured at fair value on a recurring basis.

For the year ended December 31, 2023, we recognized net losses of $35 million on equity investments from changes in fair value of the securities. We did not have equity investments in publicly traded securities with readily determinable fair values during 2022 and 2021.

In addition, as of December 31, 2023 and 2022, we had $42 million, at each balance sheet date, in equity investments without readily determinable fair values, which are recorded within other non-current assets in our consolidated balance sheets and excluded from the fair value measurement tables above.

7. Inventory

Inventory, as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Raw materials	$ 163	$ 575
Work in progress	15	205
Finished goods	24	169
Total inventory	$ 202	$ 949
Inventory, non-current[(1)]	$ 170	$ 910

[(1)]Consisted of raw materials with an anticipated consumption beyond one year. Inventory, non-current is included in other non-current assets in the consolidated balance sheets.

Inventory write-downs as a result of excess, obsolescence, scrap or other reasons, and losses on firm purchase commitments are recorded as a component of cost of sales in our consolidated statements of operations. For the years ended December 31, 2023 and 2022, inventory write-downs were $2.2 billion and $1.3 billion, respectively. Inventory write-downs were immaterial for the year ended December 31, 2021. For the years ended December 31, 2023 and 2022, losses on firm purchase commitments were $141 million and $617 million, respectively. There were no such charges in 2021. Inventory write-downs were mainly related to obsolete inventory due to shelf-life expiration and inventory in excess of expected demand. Losses on firm purchase commitments were primarily related to excess raw material purchase commitments that will expire before the anticipated consumption of those raw materials. These charges in 2023 were primarily driven by a continued shift in product demand to the latest variant-targeted COVID-19 vaccine and a decline in customer demand as the COVID-19 vaccine market continues to transition to an endemic seasonal market in 2023.

In the third quarter of 2023, we completed our long-range financial planning process, incorporating revised forecasts of vaccination rates. This resulted in the reassessment of future demand for our COVID-19 vaccine, leading to a strategic initiative to resize our manufacturing cost structure. This initiative, launched in the same quarter, involved reassessing our inventory levels and renegotiating with our suppliers to reduce our purchase commitments related to raw materials which were not expected to be consumed before expiration. This initiative resulted in a raw materials write-down of $903 million, included in the total inventory write-down amount for the quarter.

As of December 31, 2023 and December 31, 2022, the accrued liability for losses on firm future purchase commitments in our consolidated balance sheets was $79 million and $268 million, respectively. As of December 31, 2023 and December 31, 2022, we had inventory on hand of $372 million and $1.9 billion, respectively. Our raw materials and work-in-progress inventory had variable shelf lives. We expect that the majority of this inventory will be consumed over the next three years. The shelf life of our COVID-19 vaccine product ranges from nine to twelve months.

8. Property, Plant and Equipment, Net

Property, plant and equipment, net as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Land and land improvements	$ 22	$ 11
Manufacturing and laboratory equipment	345	284
Leasehold improvements	522	460
Furniture and fixtures	26	21
Computer equipment and software	74	38
Construction in progress	860	281
Right-of-use assets, financing (Note 10)	529	1,581
Total	2,378	2,676
Less: Accumulated depreciation	(433)	(658)
Property, plant and equipment, net	$ 1,945	$ 2,018

Depreciation and amortization expense for the years ended December 31, 2023, 2022, and 2021 was $617 million, $348 million, and $232 million, respectively.

9. Other Balance Sheet Components

Accounts Receivable, Net

Accounts receivable, net, as of December 31, 2023 and December 31, 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Accounts receivable	$ 1,584	$ 1,385
Less: Wholesalers chargebacks, discounts and fees	(692)	—
Accounts receivable, net	$ 892	$ 1,385

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Prepaid services	$ 182	$ 216
Down payments to manufacturing vendors	100	229
Down payments for materials and supplies	68	219
Collaboration receivable	61	11
Interest receivable	59	61
Value added tax receivable	50	140
Income tax receivable	19	10
Tenant improvement allowance receivable	—	42
Prepaid income taxes	—	187
Convertible note receivable	—	36
Other current assets	88	44
Prepaid expenses and other current assets	$ 627	$ 1,195

Other Non-Current Assets

Other non-current assets, as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Down payments and prepayments, non-current	$ 342	$ —
Inventory, non-current[(1)]	170	910
Equity investments	66	42
Goodwill	52	—
Finite-lived intangible asset	44	—
Restricted cash	4	12
Other	7	24
Other non-current assets	$ 685	$ 988

[(1)]Consisted of raw materials with an anticipated consumption beyond one year.

Accrued Liabilities

Accrued liabilities, as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Provisions related to product sales (Note 3)	$ 556	$ —
Compensation-related	245	190
Clinical trials	175	319
Manufacturing	167	400
Development operations	140	88
Other external goods and services	137	264
Royalties	122	203
Property, plant and equipment	94	5
Loss on future firm purchase commitments[(1)]	79	268
Commercial	56	48
Raw materials	27	316
Accrued liabilities	$ 1,798	$ 2,101

[(1)]Related to losses that are expected to arise from firm, non-cancellable, commitments for future raw material purchases (Note 7).

Other Current Liabilities

Other current liabilities, as of December 31, 2023 and 2022 consisted of the following (in millions):

	December 31,	
	2023	2022
Lease liabilities - financing (Note 10)	$ —	$ 161
Lease liabilities - operating (Note 10)	25	35
Other	41	53
Other current liabilities	$ 66	$ 249

Deferred Revenue

The following table summarizes the activities in deferred revenue during the year ended December 31, 2023 (in millions):

	December 31, 2022	Additions	Deductions	December 31, 2023
Net product sales	$ 2,626	$ 515	$ (2,528)	$ 613
Grant revenue	4	2	(2)	4
Collaboration revenue	81	31	(78)	34
Total deferred revenue	$ 2,711	$ 548	$ (2,608)	$ 651

10. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2042. Certain of these arrangements have free rent periods or escalating rent payment provisions. We recognize lease cost under such arrangements on a straight-line basis over the life of the leases. We have two main campuses in Massachusetts, our Cambridge campus and our Moderna Technology Center (MTC), located in Norwood. We also lease various parcels of land, office and lab spaces across the globe for our business operations.

Cambridge Campus

We occupy a multi-building campus at Technology Square in Cambridge, Massachusetts with a mix of offices and research laboratory space totaling approximately 292,000 square feet.

In September 2021, we entered into a lease agreement for a building space, approximately 462,000 square feet, in Cambridge, Massachusetts. This space is designated to be the Moderna Science Center (MSC), housing a blend of office space and laboratories. Following an approximately two-year building project, the lease term is 15 years, with options for two additional seven-year extensions. During the third quarter of 2023, we commenced the lease and recognized the related right-of-use asset and lease liability on our consolidated balance sheets. Following the commencement of the MSC lease, we amended the expiration dates of our existing leases at Technology Square in the fourth quarter of 2023. Originally scheduled to expire ranging from 2024 to 2029, these leases have been adjusted to conclude in early 2025. All our Cambridge leases are classified as operating leases.

Moderna Technology Center

We have an industrial technology center in Norwood, Massachusetts, our Moderna Technology Center (MTC), comprised of three buildings, MTC South, MTC North, and MTC East, totaling approximately 686,000 square feet. Our MTC leases expire in 2042 and we have the option to extend the term for three extension periods of five years each. All of our MTC leases are classified as finance leases.

Embedded Leases

We have entered into multiple contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. In the third quarter of 2023, as part of our strategic initiative to optimize our manufacturing footprint, we amended a contract manufacturing service agreement, resulting in decreases of $262 million in each of the right-of-use assets and lease liabilities. Additionally, it resulted in accelerated depreciation of the right-of-use assets of $323 million for the year ended December 31, 2023. As of December 31, 2023, we had no remaining right-of-use assets or lease liabilities due to embedded leases. As of December 31, 2022, we had right-of-use assets of $639 million and lease liabilities of $440 million related to embedded leases. All of our embedded leases were classified as finance leases.

Operating and financing lease right-of-use assets and lease liabilities as of December 31, 2023 and 2022 were as follows (in millions):

	December 31,	
	2023	2022
Assets:		
Right-of-use assets, operating, net[1] [2]	$ 713	$ 121
Right-of-use assets, financing, net[3] [4]	436	1,150
Total	$ 1,149	$ 1,271
Liabilities:		
Current:		
Operating lease liabilities[5]	$ 25	$ 35
Financing lease liabilities[5]	—	161
Total current lease liabilities	25	196
Non-current:		
Operating lease liabilities, non-current	643	92
Financing lease liabilities, non-current	575	912
Total non-current lease liabilities	1,218	1,004
Total	$ 1,243	$ 1,200

[1] These assets are real estate related assets, which include land, office and laboratory spaces.
[2] Net of accumulated amortization.
[3] These assets are real estate assets related to the MTC leases as well as assets related to contract manufacturing service agreements.
[4] Included in property, plant and equipment in the consolidated balance sheets, net of accumulated depreciation.
[5] Included in other current liabilities in the consolidated balance sheets.

The components of the lease costs were as follows for the periods presented (in millions):

	Years ended December 31,		
	2023	2022	2021
Operating lease costs	$ 88	$ 48	$ 24
Financing lease costs:			
Amortization of right-of-use assets, financing leases	500	280	189
Interest expense for financing lease liabilities	38	29	17
Total financing lease costs	$ 538	$ 309	$ 206
Short term lease costs	$ 2	$ —	$ 49
Variable lease costs	$ 113	$ 165	$ 100

Supplemental cash flow information relating to our leases was as follows for the periods presented (in millions):

	December 31,		
	2023	2022	2021
Cash paid for amounts included in measurement of lease liabilities:			
Operating cash flows used in operating leases	$ (93)	$ (57)	$ (19)
Operating cash flows used in financing leases	(39)	(25)	(14)
Financing cash flows used in financing leases	(292)	(184)	(140)
Operating lease non-cash items:			
Changes in right-of-use assets related to lease modifications and reassessments	$ 67	$ —	$ (7)
Right-of-use assets obtained in exchange for operating lease liabilities	714	20	72
Finance lease non-cash items:			
Changes in right-of-use assets related to lease modifications and reassessments	$ 213	$ —	$ 674
Right-of-use assets obtained in exchange for financing lease liabilities	—	777	126
Changes in financing lease liabilities	3	4	3

Weighted average remaining lease terms and discount rates as of December 31, 2023 and 2022 were as follows:

	December 31,	
	2023	2022
Remaining lease term:		
Operating leases	14 years	6 years
Finance leases	33 years	22 years
Discount rate:		
Operating leases	7.5 %	7.5 %
Finance leases	4.2 %	3.6 %

Future minimum lease payments under non-cancelable lease agreements as of December 31, 2023, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases[(1)]
2024	$ 72	$ 20
2025	67	22
2026	67	22
2027	70	23
2028	72	23
Thereafter	785	1,074
Total minimum lease payments	1,133	1,184
Less amounts representing interest	(465)	(609)
Present value of lease liabilities	$ 668	$ 575

(1) Include certain optional lease term extensions, predominantly related to the MTC leases, which represent a total of $668 million of undiscounted future lease payments.

11. Commitments and Contingencies

Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We are not currently a party to any legal proceedings for which a material loss is probable, or for which a loss is reasonably estimable at this time.

Indemnification Obligations

As permitted under Delaware law, we indemnify our officers, directors, and employees for certain events, occurrences while the officer, or director is, or was, serving at our request in such capacity. The term of the indemnification is for the officer's or director's lifetime.

We have standard indemnification arrangements in our leases for laboratory and office space that require us to indemnify the landlord against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or non-performance under our leases.

We enter into indemnification provisions under our agreements with counterparties in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited.

Through December 31, 2023 and 2022, we had not experienced any significant losses related to these indemnification obligations, and no material claims were outstanding. We do not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Purchase Commitments and Purchase Orders

We enter into agreements in the normal course of business with vendors and contract manufacturing organizations (CMOs) for raw materials and manufacturing services and with vendors for preclinical research studies, clinical trials and other goods or services. As of December 31, 2023, we had $1.8 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2029. As of December 31, 2023, $79 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments. As of December 31, 2023, we had $261 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2039. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At December 31, 2023, we had cancelable open purchase orders of $3.0 billion in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at December 31, 2023, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

Licenses to Patented Technology

In 2017, we entered into sublicense agreements with Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc. to sublicense certain patent rights. Pursuant to each agreement, we are required to pay certain license fees, annual maintenance fees, minimum royalties on future net sales and milestone payments contingent on achievement of certain development, regulatory and commercial milestones for specified products, on a product-by-product basis. Commercial milestone payments and royalties based on annual net sales of licensed products for therapeutic and prophylactic products are accounted for as additional expense of the related net product sales in the period in which the corresponding sales occur.

In December 2022, we entered into a non-exclusive patent license agreement with the National Institute of Allergy and Infectious Diseases (NIAID), an Institute or Center of the National Institutes of Health (NIH) to license certain patent rights concerning

stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products. Pursuant to the agreement, we have agreed to pay low single-digit royalties on future net sales, a minimum annual royalty payment, and certain contingent development, regulatory and commercial milestone payments on a licensed product-by-licensed product basis. In addition, in December 2022, we made a catch-up royalty payment of $400 million to NIAID, which was recorded to cost of sales in our consolidated statements of operations.

In 2023, 2022, and 2021 we recognized $301 million, $1.1 billion, and $641 million, respectively, of royalties and commercial milestone payments associated with our net product sales, which was recorded to cost of sales in our consolidated statements of operations.

Additionally, we have other in-license agreements with third parties which require us to make future development, regulatory and commercial milestone payments for specified products associated with the agreements. The achievement of these milestones have not yet occurred as of December 31, 2023.

12. Stock-Based Compensation and Share Repurchase Programs

Equity Plans

In connection with our initial public offering (IPO), we adopted the 2018 Stock Option and Incentive Plan (the 2018 Equity Plan) in November 2018. The 2018 Equity Plan became effective on the date immediately prior to the effective date of the IPO and replaced our 2016 Stock Option and Incentive Plan (the 2016 Equity Plan). The 2018 Equity Plan provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Equity Plan and the 2016 Equity Plan will be added back to the shares of common stock available for issuance under the 2018 Equity Plan.

The Board of Directors may grant to employees, nonemployee directors, consultants and independent advisors equity-based awards during their period of service, generally in the form of stock options, restricted stock units, and performance stock units. The terms and conditions of stock-based awards are defined at the sole discretion of our Board of Directors. We issue service-based awards, vesting over a defined period of service, and performance-based awards, vesting upon achievement of defined conditions. Service based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service. The remaining awards vest in twelve quarterly installments over the following twelve quarters. Stock options granted under the 2018 Equity Plan and the 2016 Equity Plan expire ten years from the date of grant and the exercise price must be at least equal to the fair market value of common stock on the grant date.

As of December 31, 2023, we had a total of 47 million shares reserved for future issuance under our Equity Plans, of which 31 million shares were reserved for equity awards previously granted, and 16 million shares were available for future grants under the 2018 Equity Plan. No additional awards will be granted under the 2016 Equity Plan as it was replaced by the 2018 Equity Plan.

Options

We have granted options generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our option activity during the year ended December 31, 2023:

	Number of Options (in millions)	Weighted Average Exercise Price per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value[(1)] (in millions)
Outstanding at December 31, 2022	24.93	$ 42.23	5.7 years	$ 3,478
Granted	4.36	113.03		
Exercised	(3.11)	8.13		
Canceled/forfeited	(0.68)	130.23		
Outstanding at December 31, 2023	25.50	56.14	5.6 years	1,437
Exercisable at December 31, 2023	18.98	33.34	4.5 years	1,378
Expected to vest at December 31, 2023	6.52	122.50	8.9 years	59

[(1)] Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of December 31, 2023.

The total intrinsic value of options exercised was $413 million, $714 million, and $1.6 billion for the years ended December 31, 2023, 2022, and 2021, respectively. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period. The excess tax benefits realized from tax deductions from option exercises were $84 million, $144 million, and $325 million during the years ended December 31, 2023, 2022, and 2021 respectively. The total consideration recorded as a result of stock option exercises was approximately $25 million, $50 million, and $112 million for the years ended December 31, 2023, 2022, and 2021.

Restricted Common Stock Units (RSUs) and Performance Stock Units (PSUs)

We have granted RSUs and PSUs generally through the 2018 Equity Plan. The following table summarizes our RSU and PSU activity during the year ended December 31, 2023:

	Number of Units (in millions)	Weighted Average Grant Date Fair Value per Unit
Outstanding, non-vested at December 31, 2022	2.90	$ 132.25
Issued	3.71	107.23
Vested	(1.01)	98.68
Canceled/forfeited	(0.42)	130.01
Outstanding, non-vested at December 31, 2023	5.18	121.02

The total grant date fair value of RSUs and PSUs vested during the years ended December 31, 2023, 2022, and 2021, was $99 million, $55 million, and $18 million, respectively. The total intrinsic value of RSUs and PSUs vested during the years ended December 31, 2023, 2022, and 2021, was $120 million, $125 million and $141 million, respectively.

During 2023, 2022 and 2021, we granted an immaterial amount of PSUs, respectively, primarily to certain senior executives with vesting that is contingent upon the achievement of specified preestablished goals over the performance period, generally three years. The actual number of common shares ultimately issued is calculated by multiplying the number of PSUs by a payout percentage ranging from 0% to 200%. The estimated fair value of PSUs is based on the grant date fair value.

Valuation and Stock-Based Compensation Expense

Stock-based compensation for options granted under our Equity Plans is determined using the Black-Scholes option pricing model. The weighted-average assumptions used to estimate the fair value of options granted for the years ended December 31, 2023, 2022, and 2021 were as follows:

	Weighted Average Years Ended December 31,		
	2023	2022	2021
Options:			
Risk-free interest rate	4.13 %	2.46 %	0.84 %
Expected term	6.07 years	6.13 years	6.10 years
Expected volatility	48 %	50 %	46 %
Expected dividends	— %	— %	— %
Weighted average fair value per share	$ 57.87	$ 76.02	$ 91.84

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense for the years ended December 31, 2023, 2022, and 2021 (in millions):

	Years Ended December 31,		
	2023	2022	2021
Options	$ 136	$ 123	$ 96
RSUs and PSUs	161	97	42
Employee stock purchase plan	8	6	4
Total	$ 305	$ 226	$ 142
Cost of sales	$ 37	$ 45	$ 22
Research and development	157	93	68
Selling, general and administrative	111	88	52
Total	$ 305	$ 226	$ 142

For the years ended December 31, 2023, 2022, and 2021, we recognized stock-based compensation expense of $17 million, $18 million, and $16 million, respectively, related to performance-based awards, including awards with vesting or commencement contingent upon our IPO. Stock-based compensation expenses related to non-employee awards were immaterial for the years ended December 31, 2023, 2022, and 2021.

As of December 31, 2023, there were $835 million of total unrecognized compensation cost related to non-vested stock-based compensation with respect to options, RSUs and PSUs granted. That cost is expected to be recognized over a weighted-average period of 2.6 years at December 31, 2023.

Share Repurchase Programs

On August 2, 2021, our Board of Directors authorized a Share Repurchase Program (2021 Repurchase Program) of our common stock, with an expiration date no later than August 2, 2023. Pursuant to the 2021 Repurchase Program, we were authorized to repurchase up to $1.0 billion of our outstanding common stock. By the end of January 2022, we had repurchased the entire $1.0 billion of common stock that was authorized under the 2021 Repurchase Program. On February 22, 2022, our Board of Directors authorized an additional share repurchase program of our common stock, with no expiration date, for up to $3.0 billion. On August 1, 2022, our Board of Directors authorized an increase of $3.0 billion under the repurchase program for our common stock, with no expiration date (collectively with the February 22, 2022 authorization, the 2022 Repurchase Programs).

As of December 31, 2023, $1.7 billion of our Board of Directors' authorization for repurchases of our common stock remains outstanding (the 2022 Repurchase Programs), with no expiration date. The timing and actual number of shares repurchased under the 2022 Repurchase Programs will depend on a variety of factors, including price, general business and market conditions, and other investment opportunities, and shares may be repurchased through open market purchases through the use of trading plans intended to qualify under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended.

The following table summarizes activity related to our share repurchase programs (in millions, except per share data):

	Years Ended December 31,		
	2023	2022	2021
Number of shares repurchased	8	23	3
Average price per share[(1)]	$ 143.26	$ 142.83	$ 245.76
Aggregate purchase price	$ 1,153	$ 3,329	$ 857
Remaining authorization at end of period	$ 1,667	$ 2,814	$ 143

[(1)]Average price paid per share includes related expenses and excise tax, applicable beginning January 1, 2023.

13. Income Taxes

(Loss) income before income taxes for the years ended December 31, 2023, 2022, and 2021 consisted of the following (in millions):

	Years Ended December 31,		
	2023	2022	2021
United States	$ (4,056)	$ 9,433	$ 13,108
Foreign	114	142	177
(Loss) income before income taxes	$ (3,942)	$ 9,575	$ 13,285

The provision for income taxes for the years ended December 31, 2023, 2022, and 2021 consisted of the following components (in millions):

	Years Ended December 31,		
	2023	2022	2021
Current:			
Federal	$ (225)	$ 1,687	$ 1,304
State	72	47	35
Foreign	24	57	40
Total current	$ (129)	$ 1,791	$ 1,379
Deferred:			
Federal	$ 888	$ (569)	$ (288)
State	8	(7)	(6)
Foreign	5	(2)	(2)
Total deferred	901	(578)	(296)
Total provision for income taxes	$ 772	$ 1,213	$ 1,083

The reconciliation of the federal statutory income tax rate to our effective tax rate for the years ended December 31, 2023, 2022, and 2021 was as follows:

	Years Ended December 31,		
	2023	2022	2021
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Change in valuation allowance	(52.6)%	— %	(5.4)%
Foreign-derived intangible income	0.2 %	(7.4)%	(4.8)%
Stock-based compensation windfall	2.4 %	(1.6)%	(2.6)%
Federal research and development credits	4.6 %	(0.5)%	(0.7)%
State taxes, net of federal benefits	5.7 %	0.4 %	0.5 %
Non-deductible items	(0.4)%	— %	— %
Other	(0.5)%	0.8 %	0.1 %
Effective tax rate	(19.6)%	12.7 %	8.1 %

Our effective tax rate for the year ended December 31, 2023 was (19.6)% and was higher than the federal statutory tax rate, primarily due to an increase in valuation allowance against deferred tax assets. The effective tax rates for the year ended December 31, 2023 also include tax benefits from research and development credits and stock-based compensation. Our effective tax rate for the year ended December 31, 2022 was lower than the federal statutory tax rate, primarily due to the tax benefit of the foreign-derived intangible income deduction (FDII) and excess tax benefit related to stock-based compensation. Our effective tax rate for the year ended December 31, 2021 was lower than the federal statutory tax rate, primarily due to the tax benefits related to the release of the valuation allowance on most of our deferred tax assets, FDII and stock-based compensation.

As of January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017 ("TCJA"), research and development costs in the current period are required to be amortized over five or fifteen years, depending on where the research is conducted. The new capitalization requirement significantly increased our deferred tax assets and cash tax liabilities, but also decreased our effective tax rate by increasing the foreign-derived intangible income deduction.

The President signed into law the Inflation Reduction Act (the "IRA") on August 16, 2022. The Act includes a new 15% corporate minimum tax and a 1% excise tax on the value of corporate stock repurchases, net of new share issuances, after December 31, 2022. We do not expect these provisions to have a material impact on our consolidated financial position; however, we will continue to evaluate their impact as further information becomes available.

Deferred income taxes reflect the tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes, tax credit carryforwards and the tax effect of net operating loss carryforwards. Significant components of our deferred tax assets and tax liabilities as of December 31, 2023 and 2022 were as follows (in millions):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 90	$ 59
Stock-based compensation	111	68
Capitalized licenses, research and development and start-up costs	1,449	704
Tax credit carryforwards	140	97
Operating lease liabilities	154	26
Financing lease liabilities	139	135
Other comprehensive income	34	106
Inventory reserve and capitalization	250	86
Wholesaler chargebacks, discounts and fees	92	—
Returns and other fees	129	—
Other	90	85
Total deferred tax assets	2,678	1,366
Less: valuation allowance	(2,224)	(155)
Net deferred tax assets	$ 454	$ 1,211
Deferred tax liabilities:		
Right-of-use assets, financing	$ (106)	$ (117)
Right-of-use assets, operating	(160)	(26)
Property, plant and equipment	(107)	(85)
Other	(15)	(1)
Total deferred tax liabilities	(388)	(229)
Net deferred tax (liabilities) assets	$ 66	$ 982

The table below summarizes changes in the valuation allowance for deferred tax assets for the periods presented (in millions):

	Years Ended December 31,		
	2023	2022	2021
Valuation allowance at beginning of the period	$ 155	$ 149	$ 823
Decreases recorded as benefit to income tax provision	—	(12)	(722)
Increases to valuation allowance	2,069	18	48
Valuation allowance at December 31	$ 2,224	$ 155	$ 149

We periodically reassess the need for valuation allowances on our deferred tax assets, considering both positive and negative evidence to evaluate whether it is more likely than not that all or a portion of such assets will not be realized. During 2023, following the completion of our long-range financial planning process, we reassessed the evidence and concluded that a valuation allowance was necessary due to the preponderance of negative evidence, including:

- A pre-tax loss for the full year 2023, serving as a significant source of objectively verifiable negative evidence in accordance with ASC 740 (Income Taxes).
- A projected three-year cumulative loss resulting from our long-range financial planning process. This projection is due to a significant decrease in expected sales of our COVID-19 vaccine as we transition to a seasonal market. Additionally, we anticipate substantial research and development expenses for our on-going Phase 3 clinical trials and to advance our product candidates into later-stage development. These factors contribute additional negative evidence with respect to the realizability of our deferred tax assets. The projections are based upon revenue from our currently approved drug product, which we believe can be reasonably estimated. In contrast, future taxable income projections from our investigational medicines are deemed inherently subjective and not objectively verifiable; they are insufficient to override negative evidence, and therefore, they are not assigned any weight in our valuation allowance analysis assessment.

Our evaluation also included whether there were other sources of taxable income that would allow us to realize our deferred tax assets, such as taxable income in carryback years, available tax planning strategies and the future reversals of taxable temporary differences. After assessing these strategies and all evidence, we determined it was more likely than not that we will not realize all of our deferred tax assets and therefore increased the valuation allowance by $2.1 billion during 2023.

In the first quarter of 2021, we reassessed the valuation allowance noting the increase in positive evidence, including significant revenue growth, expectations regarding future profitability, and successful supply chain and manufacturing capabilities to meet global product demand. After assessing both the positive evidence and negative evidence, we determined it was more likely than not that we would realize the majority of our deferred tax assets, and we released the valuation allowance on the majority of our deferred tax assets, accordingly. The release of the valuation allowance was based on the then-prevailing positive outlook, which has since shifted significantly by 2023 due to the factors outlined above, leading to the reinstatement of a full valuation allowance.

Significant management judgment is required in assessing the realizability of our deferred tax assets. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to modify our valuation allowance, which could materially impact our financial position and results of operations.

At December 31, 2023, we had $1.6 billion of state net operating loss carryforwards, which begin to expire in 2030. At December 31, 2023, we also had state research and development tax credit carryforwards of $178 million, the majority of which will begin to expire in 2030.

We recognize, in our financial statements, the effect of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. A reconciliation of the beginning and ending amounts of unrecognized tax benefits during the years ended December 31, 2023, 2022, and 2021 were as follows (in millions):

	Years Ended December 31,		
	2023	2022	2021
Unrecognized tax benefits at beginning of the period	$ 128	$ 68	$ —
Decrease due to prior positions:			
Tax positions for prior years	—	(1)	—
Expiration of statutes	—	—	—
Settlements with tax authorities	(27)	—	—
Increase due to current year tax positions:			
Additions based on tax positions for current year	44	57	54
Additions based on tax positions for prior years	86	4	14
Unrecognized tax benefits at end of the period	$ 231	$ 128	$ 68

As of December 31, 2023, we had $231 million of net unrecognized tax benefits, which would affect our tax rate if recognized. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business. We do not anticipate a material change to our unrecognized tax benefits over the next twelve months that would have an adverse effect on our consolidated operating results. We recognize interest and penalties, if applicable, related to uncertain tax positions as a component of income tax expense.

We file U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. All tax years since our date of incorporation remain open to examination by the major taxing jurisdictions, as carryforward attributes generated in past years may be adjusted upon examination by the Internal Revenue Service or the state authorities. There are no open tax examinations at this time.

14. (Loss) Earnings per Share

The computation of basic earnings (loss) per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and potential dilutive common shares outstanding during the period as determined by using the treasury stock method.

Basic and diluted EPS for the years ended December 31, 2023, 2022 and 2021 were calculated as follows (in millions, except per share data):

	Years Ended December 31,		
	2023	2022	2021
Numerator:			
Net (loss) income	$ (4,714)	$ 8,362	$ 12,202
Denominator:			
Basic weighted-average common shares outstanding	382	394	403
Effect of dilutive securities	—	22	28
Diluted weighted-average common shares outstanding	382	416	431
Basic EPS	$ (12.33)	$ 21.26	$ 30.31
Diluted EPS	$ (12.33)	$ 20.12	$ 28.29

The following common stock equivalents, presented based on amounts outstanding as of December 31, 2023, 2022 and 2021, were excluded from the calculation of diluted net (loss) income per share attributable to common stockholders for the periods indicated because their inclusion would have been anti-dilutive (in millions):

	December 31,		
	2023	2022	2021
Options	26	3	1
RSUs and PSUs	5	—	—
Total	31	3	1

15. Geographic Information

Geographic Revenue

We operate in one reporting segment that primarily focuses on the discovery, development and commercialization of mRNA medicines. Our chief executive officer manages our operations and evaluates our financial performance on a consolidated basis. Most of our principal operations, other than manufacturing, and our decision-making functions are located at our corporate headquarters in the United States.

Total revenue by geographic area of our customers and collaboration partners was as follows (in millions):

	Years Ended December 31,		
	2023	2022	2021
United States	$ 1,895	$ 5,150	$ 6,177
Europe	1,355	6,815	6,846
Rest of world	3,598	7,298	5,448
Total	$ 6,848	$ 19,263	$ 18,471

Our property, plant and equipment, including financing right-of-use assets, by geographic area was as follows (in millions):

	December 31,	
	2023	2022
United States	$ 1,560	$ 1,267
Europe	126	714
Rest of world	259	37
Total	$ 1,945	$ 2,018

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Management assessed our internal control over financial reporting as of December 31, 2023. Management based its assessment on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

During the three months ended December 31, 2023, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believe that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by a management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Moderna, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Moderna, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Moderna, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 23, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 23, 2024

Item 9B. Other Information

10b5-1 Plans

On November 7, 2023, Noubar Afeyan, our Chairman, amended a trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Afeyan 10b5-1 Plan). The Afeyan 10b5-1 Plan was amended to increase certain price triggers under the plan. The Afeyan 10b5-1 Plan, as amended, is scheduled to commence on February 28, 2024, and will run through August 20, 2025. The aggregate maximum number of shares of common stock that may be sold pursuant to the Afeyan 10b5-1 Plan is 745,000, which represents the shares remaining under the original plan that have not been sold to date.

On November 6, 2023, Arpa Garay, our former Chief Commercial Officer, terminated a trading arrangement that was intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Garay 10b5-1 Plan). The Garay 10b5-1 Plan was entered into on August 24, 2023, and was scheduled to commence on November 27, 2023, with a termination date of August 30, 2024. The Garay 10b5-1 Plan provided for the potential sale of approximately 4,540 shares of common stock and for the potential exercise of vested stock options and the associated sale of up to 24,897 shares. No shares of common stock were sold, and no options to purchase shares of common stock were exercised, under the Garay 10b5-1 Plan prior to its termination.

Amended and Restated By-laws

On February 21, 2024, our Board of Directors approved and adopted the Company's Second Amended and Restated By-laws (the "By-laws"), which became effective immediately. The By-laws supersede and replace in their entirety the Company's Amended and Restated By-laws in effect immediately prior to effectiveness of the By-laws.

The By-laws, among other things:

- implement a majority voting standard in uncontested director elections;
- implement a proxy access provision, which permits a stockholder, or a group of up to 20 stockholders, owning 3% of our outstanding common stock continuously for at least three years to nominate and include in our proxy materials director candidates constituting up to the greater of two nominees or 20% of the Board of Directors, subject to the terms and conditions set forth in the By-laws;
- update our advance notice provisions to take into account recent rules adopted by the SEC regarding usage of universal proxies;
- reflect recent amendments and updates to the Delaware General Corporation Law; and
- incorporate certain other administrative, technical, clarifying and conforming changes.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the full text of the By-laws, a copy of which is attached hereto as Exhibit 3.2 and is incorporated herein by reference.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

Our independent public accounting firm is Ernst & Young LLP, Boston, Massachusetts, PCAOB Auditor ID 00042.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

(1) Financial statements.

For a list of the consolidated financial statements included herein, see "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

(3) Exhibits.

Exhibit No.	Exhibit Index
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (2)
3.2*	Second Amended and Restated By-laws of the Registrant.
4.1	Specimen Common Stock Certificate. (1)
4.2	Description of Capital Stock. (4)
10.1#	2016 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder. (1)
10.2#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder. (1)
10.3#	Form of Indemnification Agreement between the Registrant and each of its directors. (1)
10.4†	Master Collaboration and License Agreement, by and between Moderna Therapeutics, Inc. and Merck Sharp & Dohme Corp., dated as of January 12, 2015, as amended by Amendment No. 1 dated as of January 8, 2016, Amendment No. 2 dated as of June 28, 2016, Amendment No. 3 dated as of June 28, 2016 and Amendment No. 4 dated as of June 28, 2016. (1)
10.5†	Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement, by and between ModernaTX, Inc. and Merck Sharp & Dohme Corp., dated as of April 17, 2018. (1)
10.6†	Patent Sublicense Agreement, by and among ModernaTX, Inc. and Cellscript, LLC and mRNA RiboTherapeutics, Inc. (solely with respect to certain provisions), dated as of June 26, 2017. (1)
10.7	Net Lease by and between Moderna Therapeutics, Inc. and Campanelli-TriGate Norwood Upland, LLC, dated as of August 29, 2016, as amended by Amendment No. 1 dated as of April 10, 2017 and Amendment No. 2 dated as of March 16, 2018. (1)
10.8	Third Amendment, dated September 11, 2018, Fourth Amendment, dated March 28, 2019, and Omnibus Amendment, dated December 30, 2021, to Net Lease, dated as of August 29, 2016, as amended. (5)
10.9#	Amended and Restated Executive Severance Plan and Form of Participation Letter, as amended on February 23, 2023. (9)
10.10#	Letter Agreement by and between the Company and Stéphane Bancel, dated as of June 13, 2018, as amended by Amendment No. 1 dated as of November 4, 2018. (1)
10.11#	Letter Agreement by and between the Company and Stephen Hoge, dated as of October 17, 2017. (1)
10.12#	Employment Letter Agreement between ModernaTX, Inc. and Shannon Klinger, dated as of March 4, 2021. (5)
10.13#	Offer Letter by and between ModernaTX, Inc. and James Mock, dated as of August 15, 2022. (8)
10.14#	Offer Letter by and between ModernaTX, Inc. and Arpa Garay, dated as of April 21, 2022. (9)
10.15#*	Executive Separation and Transitional Services Agreement, January 2, 2024, between ModernaTX, Inc. and Arpa Garay.
10.16#	Updated Executive Retirement and Strategic Consulting Agreement, dated May 27, 2022, between ModernaTX, Inc. and David Meline. (7)
10.17#	Executive Separation Agreement and Release, dated May 13, 2022, between ModernaTX, Inc. and Jorge Gomez. (6)
10.18#	Senior Executive Cash Incentive Bonus Plan. (1)
10.19#	Amended and Restated Non-Employee Director Compensation Policy, effective October 1, 2022. (8)

10.20#	Form of Indemnification Agreement between the Registrant and each of its officers. (1)
10.21#*	2018 Employee Stock Purchase Plan.
10.22#*	Form of Employee Restricted Stock Unit Award Agreement.
10.23#*	Form of Employee Non-Qualified Stock Option Agreement.
10.24#	Form of Non-Employee Director Restricted Stock Unit Award Agreement. (5)
10.25#	Form of Non-Employee Director Non-Qualified Stock Option Agreement. (5)
10.26#	Form of Performance-Based Restricted Stock Unit Award Agreement under the 2018 Stock Option and Incentive Plan. (3)
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97*	Moderna, Inc. Policy for Recoupment of Executive Incentive Compensation.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

† Pursuant to 17 C.F.R. §§230.406 and 230.83, the confidential portions of this exhibit have been omitted and are marked accordingly.

# Indicates a management contract or any compensatory plan, contract or arrangement.

+ The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

(1) Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-228300) filed with the Securities and Exchange Commission on November 9, 2018.

(2) Incorporated by reference to the Current Report on Form 8-K (File No. 001-38753) filed with the Securities and Exchange Commission on December 14, 2018.

(3) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on May 6, 2021.

(4) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38753) filed with the Securities and Exchange Commission on February 27, 2020.

(5) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38753) filed with the Securities and Exchange Commission on February 25, 2022.

(6) Incorporated by reference to the Current Report on Form 8-K/A (File No. 001-38753) filed with the Securities and Exchange Commission on May 13, 2022.

(7) Incorporated by reference to the Current Report on Form 8-K/A (File No. 001-38753) filed with the Securities and Exchange Commission on June 1, 2022.

(8) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on November 3, 2022.

(9) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38753) filed with the Securities and Exchange Commission on February 24, 2023.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MODERNA, INC.

Date:
February 23, 2024

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints each of Stéphane Bancel and James M. Mock as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stéphane Bancel Stéphane Bancel	Chief Executive Officer and Director *(Principal Executive Officer)*	February 23, 2024
/s/ James M. Mock James M. Mock	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 23, 2024
/s/ Noubar B. Afeyan, Ph.D. Noubar B. Afeyan, Ph.D.	Chairman and Director	February 23, 2024
/s/ Stephen Berenson Stephen Berenson	Director	February 23, 2024
/s/ Sandra Horning, M.D. Sandra Horning M.D.	Director	February 23, 2024
/s/ Robert Langer, Sc.D. Robert Langer, Sc.D.	Director	February 23, 2024
/s/ Francois Nader, M.D. Francois Nader M.D.	Director	February 23, 2024
/s/ Elizabeth Nabel, M.D. Elizabeth Nabel, M.D.	Director	February 23, 2024
/s/ Paul Sagan Paul Sagan	Director	February 23, 2024
/s/ Elizabeth Tallett Elizabeth Tallett	Director	February 23, 2024

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moderna

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modernatx.com

Transfer Agent:
Computershare Trust Company, N.A.

Audit Firm:
Ernst & Young, LLP